
Psycho-social impacts of malocclusion and orthodontic treatment in adolescent patients

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**Submitted for
The Degree of Doctor in Philosophy in Clinical Dentistry
(Orthodontics)
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Abstract

Introduction: Malocclusion may have an impact on psycho-social aspects but the evidence is less clear cut regarding the potential benefits associated with orthodontic treatment. This PhD therefore aimed to study these aspects in 3 chapters:

Systematic review

Aims: To evaluate social, psychological and quality of life changes due to orthodontic treatment.

Methods, Results and Conclusions: Six electronic databases were searched and 21 articles included, reporting results of RCTs and observational studies. There was inadequate evidence to support or refute that orthodontic treatment in adolescent patients has positive psychosocial effects. The lack of a universal outcome measure in reporting impacts of orthodontic treatment is an important issue, so efforts must be made to develop this measure.

Prospective controlled longitudinal study

Aims: To study social impacts following functional appliance in adolescent with Class II Division 1 malocclusions and to compare it with a control group of patients of the same age range who had not yet commenced treatment.

Methods: Participants completed a questionnaire regarding social impacts before and after functional appliance treatment.

Results: 114 patients were recruited, 65 patients in the treatment group and 49 patients in the control group. There was no statistically significant difference between the groups at T2.

Conclusions: Based on the questionnaires used, there were no significant social benefits associated with functional appliance treatment.

Qualitative study

Aims: To explore the social impacts of malocclusion in adolescent patients using qualitative methods.

Methods: In-depth interviews were conducted and data were analysed using a framework analysis.

Results: 12 participants were interviewed and three main themes were identified: Interpersonal relations, feelings regarding facial images and teasing.

Conclusions: Although common themes were identified, variation existed with regards to the social effects of malocclusion on an adolescent's lifestyle. Interviewees reported being repeatedly reminded of their malocclusion; reinforced through teasing and images in different media.

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List of Abbreviations

CPQ	Child Perception Questionnaire
DAI	Dental Aesthetic Index
GRADE system	Grades of Recommendation, Assessment, Development and Evaluation Working Group
HRQoL	Health Related Quality of Life
IOTN	Index of Orthodontic Treatment Need
IOTN-AC	Index of Orthodontic Treatment Need-Aesthetic Component
IOTN-DHC	Index of Orthodontic Treatment Need-Dental Health Component
MSCS	Multidimensional Self-Concept Scale
OASIS	Oral Aesthetic Subjective Impact Scale
OH	Oral Health
OHIP	Oral Health Impact Profile
OHRQoL	Oral Health Related Quality of Life
SAD	Social Anxiety Disorder
SAS-A	Social Anxiety for Adolescents
PIL	Participants Information Leaflet
QoL	Quality of Life
WHO	The World Health Organization

Chapter I: An introduction to the psycho-social and quality of life impacts of malocclusion and orthodontic treatment in adolescents

Epidemiology of malocclusion

Definition of malocclusion

The World Health Organization includes malocclusion under the heading of a Handicapping Dentofacial Anomaly and defines it as "an anomaly which causes disfigurement or which impedes function, and requiring treatment if the disfigurement or functional defect is likely to be an obstacle to the patient's physical or emotional well-being" (World Health Organisation, 1987, cited in Hassan and Rahimah, 2007).

Incidence/Prevalence of malocclusion

Malocclusion is considered one of the most common oral conditions (Zhang *et al.*, 2006). It has a multifactorial nature, with genetic factors, environmental factors or a combination of the two being implicated (Corruccini, 1984; Normando *et al.*, 2013). It is reported that the incidence of malocclusion ranges from 39% to 93% depending on where the study is undertaken and the classification used (Thilander *et al.*, 2001). Epidemiological research undertaken by Holmes (1992) indicated that approximately one third of 12 year-olds in the United Kingdom (UK) would benefit from orthodontic treatment, while McLain and Proffit (1985) in the United States (US) reported that 70% of the population was affected by some form of malocclusion.

Orthodontic treatment need

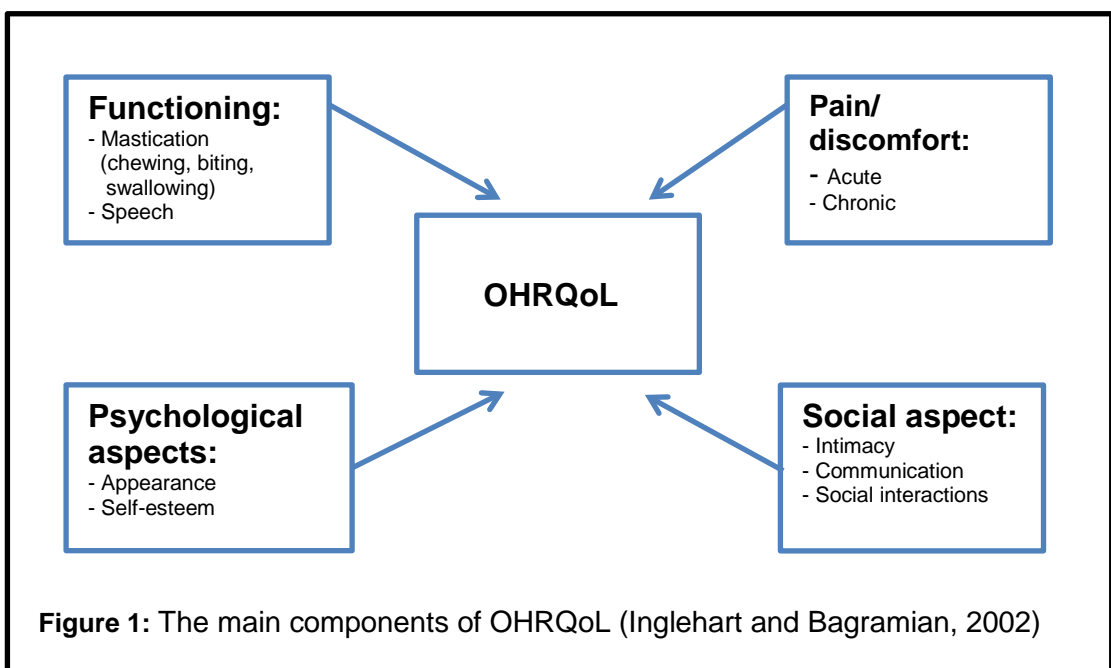
Orthodontic treatment need is commonly assessed using clinical tools, such as the Index of Orthodontic Treatment Need (IOTN) (Brook and Shaw, 1989) or the Dental Aesthetic Index (DAI) (Cons *et al.*, 1986 cited in Jenny and Cons, 1996a). These tools are important as clinical indicators, but there is an increasing recognition that they require supplementation with Oral Health Related Quality of Life (OHQoL) instruments because clinical findings may not correlate with the extent of patient concern (McGrath *et al.*, 2004).

Conceptual Background of Oral Health Related Quality of Life

Terminology: Health, oral health and quality of life

In 1946, the World Health Organization defined health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (World Health Organisation, 1946). Subsequently, in 1994 the Department of Health in England defined oral health as “the standard of oral and related tissue health which enables an individual to eat, speak and socialise without active disease, discomfort, or embarrassment, and which contributes to general wellbeing” (Public Health England, 1994). Therefore, good oral health does not mean purely the absence of oral diseases and the presence of dysfunction; it also includes aspects such as quality of life.

In 1997, Locker described the shift in health care from a disease-based to a patient-based approach. Locker (1997) stated that quality of life (QoL) is broader than health, and is based on characteristics of the person and also non-medical factors. Then in 2002, Inglehart and Bagramian suggested that health related quality of life (HRQoL) could be defined as “a person’s assessment of how the following affect his or her well-being: (1) functional factors (2) psychological factors (concerning a person’s appearance and self-esteem) (3) social factors (such as interactions with others) and (4) the experience of pain/discomfort”. This definition broadly represents the central dimensions of OHRQoL (Figure 1). Therefore, OHRQoL can be defined as “the absence of negative effects of oral conditions on social life and a positive sense of dentofacial satisfaction” (Inglehart and Bagramian, 2002).



These definitions led to the development of a multidimensional approach to OHRQoL, including physical, psychological and social functioning, which help to complete the whole picture of oral health (de Oliveira and Sheiham, 2003).

Orthodontic treatment results in the alignment of teeth and correction of dental relationships, with the aim of improving dental health, function and aesthetics, and as a result of this it may also enhance quality of life and other psycho-social aspects of a patient's life. This has led researchers to study the relationship between malocclusion, orthodontic treatment and quality of life (de Oliveira and Sheiham, 2004; Cunningham and O'Brien, 2007; Johal *et al.*, 2007; O'Brien *et al.*, 2009; Liu *et al.*, 2009; Mandall *et al.*, 2012; Seehra *et al.*, 2013; Zhou *et al.*, 2014a; Benson *et al.*, 2015; Kragt *et al.*, 2015). This is important for patients and clinicians, but it is also important for health care providers, health planners and researchers. Increasingly, there is a need to justify the provision of orthodontic treatment and to investigate the benefits of treatment; therefore there is a need for instruments to measure social and psychological factors (Cunningham and O'Brien, 2007).

A variety of oral health related quality of life (OHRQoL) instruments are now available to provide information about the effects of the malocclusion and the impact of orthodontic treatment. Those which have been shown to have good psychometric properties include the Child Perception Questionnaire (CPQ) (Jokovic *et al.*, 2002) and the Oral Health Impact Profile (OHIP) (Slade and Spencer, 1994). However, it must be noted that these questionnaires were not developed specifically for malocclusion and/or orthodontics and the OHIP was not developed for children/adolescents. Recently, the Malocclusion Impact Questionnaire (MIQ) was developed by Benson *et al.* (2016) and Patel *et al.* (2016) specifically for malocclusion and orthodontic treatment in adolescents. This is considered an important step in the development of a valid age-specific instrument, which could be used internationally for QoL studies in orthodontics. This will help to investigate the psycho-social and OHRQoL impacts associated with malocclusion and orthodontic treatment using appropriate questionnaires.

Similar to the paradigm shift in OHRQoL in recent years, orthodontic treatment outcomes have moved from being purely physical to also having a psycho-social focus. There are always subjective and objective aspects to treatment and the literature shows potential benefits, including improvement in dental health, function, appearance and self-confidence/self-esteem. It must however be acknowledged that

the quality of the evidence base in this area is not strong, partly due to the limitations in the types of studies which can be undertaken due to ethical reasons. From a patient and a public health perspective, the benefits of treatment must outweigh the financial costs and the possible risks and disadvantages of treatment (Helm *et al.*, 1985; Shaw *et al.*, 1991). Some of the main effects of malocclusion and orthodontic treatment and their relationship with OHRQoL which have been discussed in the literature are collated in Figure 2 on the following page.

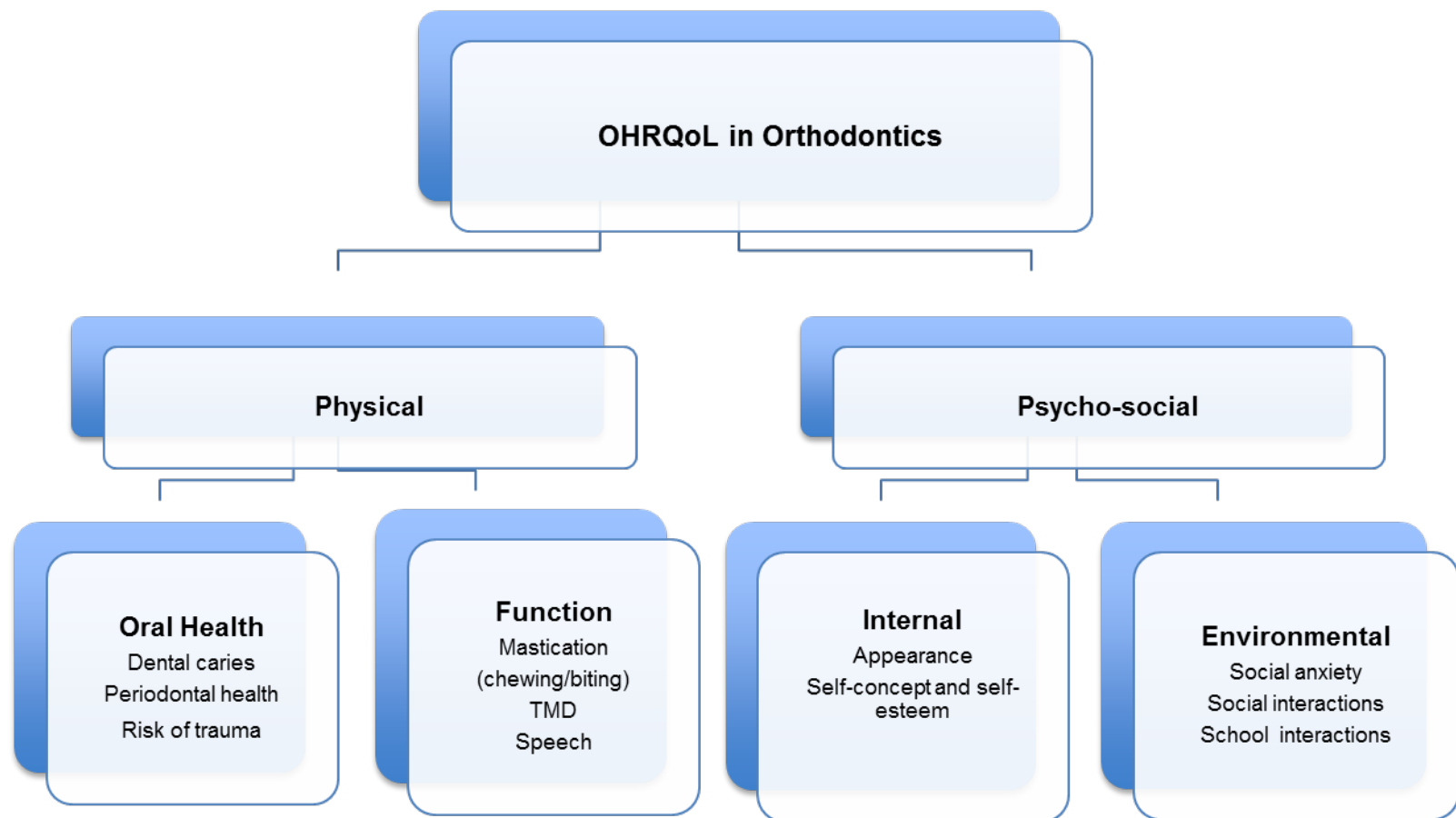


Figure 2: OHRQoL in Orthodontics

Oral Health Related Quality of Life & Orthodontics in adolescents

Physical effects

The physical effects of malocclusion and orthodontic treatment will not be considered here as they are not the focus of this PhD.

Psycho-social effects

Adolescence is a period of transition from childhood to adulthood and from parental influence to peer influence. The impact of adolescent life events in the prediction of psycho-social health has been suggested in several studies. In New York, a study conducted by Pine *et al.* (2002) found that certain negative life events in adolescents were considered as predictors for depression during adulthood. Furthermore, satisfactory peer relationships are seen as being important for successful social and emotional development and the importance of first impressions (including the face, smile and teeth) appears to be significant for communication (Josefsson *et al.*, 2010). Therefore, the relationship between dentofacial appearance and psycho-social impacts is important, because aesthetic perceptions differ from one person to another, depending on their personal experiences and social environment. Identifying the risk factors for potential psycho-social problems is important in order to improve the health of adolescents and to reduce negative impacts on daily life. However, some patients believe that malocclusion is a barrier to their social life and may have unrealistic expectations of orthodontic treatment; such patients therefore need to be managed very carefully (O'Brien *et al.*, 2003).

Internal effects

I. Appearance

Dental aesthetics is one of the important aspects of facial appearance. The impact of dentofacial appearance on social relationships has been reported in a number of different studies. Adolescents are thought to show concern about their faces and bodies because they want to present a good physical appearance and this is considered an important personal characteristic (Prokhorov *et al.*, 1993). Dental appearance may also have social and psychological influences in life (Helm *et al.*, 1985) and it has been suggested that treatment of malocclusion to improve dental

appearance, may lead to other effects including social acceptance, although the extent of this social impact is not clear.

It has long been found that the majority of people who seek orthodontic treatment do so for aesthetic reasons rather than to address dental health problems (Shaw *et al.*, 1980b; Albino *et al.*, 1981; Dann *et al.*, 1995). Helm *et al.* (1985) found higher levels of dissatisfaction in patients with overjets greater than 9mm, overbites greater than 7mm and crowding. Another study investigated the prevalence of malocclusion, and its association with oral aesthetic self-perception in young adults. Patients with severe malocclusions showed an 88% higher prevalence of poorer aesthetic self-perception compared with those with minor malocclusion (Claudino and Traebert, 2013).

A number of studies have investigated the impact of dental appearance including a longitudinal study in Norway by Birkeland *et al.* (2000). The authors investigated the association between malocclusion and satisfaction with dental appearance in adolescent patients. A total sample of 224, 11 year olds were examined at T1 and the dental casts were assessed using the IOTN-AC and IOTN-DHC. Children and their parents also completed questionnaires, including an orthodontic concern questionnaire and the Global Negative Self-Evaluation Scale. When the children were followed up 4 years later (T2), 16 children had been treated with removable appliances and 51 with fixed appliances, whilst 157 were untreated. The results showed that the fixed appliance group had better aesthetics (AC) and occlusion (DHC) ($p < 0.001$) than the other two groups. Additionally, both children and their parents reported significantly increased satisfaction with dental appearance after orthodontic treatment ($p < 0.001$). The authors concluded those children and their parents thought that good dental aesthetics are essential for psychological well-being.

A recent systematic review by Samsonyanova and Broukal (2014) investigated the main motivating factors for parents seeking orthodontic treatment for their children. The authors used 3 databases: Medline, Embase and Google Scholar, and all relevant papers up to 2013 were selected, including cross sectional studies, longitudinal studies, randomised controlled trials, systematic reviews and meta analyses. There were 13 papers which were eligible for inclusion and it was found that aesthetics and dissatisfaction with one's appearance were the main motivating factors for treatment. Other factors were also reported including dental crowding

(especially anterior maxillary crowding), large overjets, missing teeth and a wish for their children to look nice. The authors highlighted that identifying these factors helps to establish treatment priorities.

Individuals may assess aesthetics differently, depending on their cultural and/or social background. A study to assess this was conducted by Mtaya *et al.* (2008) in Tanzanian schoolchildren. A sample of 1601 children (mean age 13 years) completed the Child-OIDP questionnaire. Additionally, face-to-face interviews were undertaken to assess dental problems and dissatisfaction with dental appearance/function. The authors concluded that, despite the high prevalence of malocclusion, (63.8% of participants were assessed as having at least one type of malocclusion) the psycho-social impacts and dissatisfaction with dental appearance/function were not frequent in Tanzanian schoolchildren and only occurred in 23.3% of participants.

By contrast, Feu *et al.* (2012) conducted a study to examine aesthetic self-perception in Brazilian adolescents. A sample of 318 adolescents aged 12 to 15 years, were classified into groups: an orthodontic treatment group (n=92 patients) and a control group of untreated participants (n=226, 102 control subjects from schools and 124 subjects who were on the waiting list for treatment). The Index of Orthodontic Treatment Need-Aesthetic Component (IOTN-AC) was used as a measure of aesthetic self-perception. The subjects were interviewed at 3 time points: baseline (T1), after the first year (T2) and after the second year of treatment (T3). The authors reported that the aesthetic self-perception scores showed a statistically significant improvement ($p < 0.01$) in the treatment group but a deterioration (albeit not significant at $p = 0.08$) for the waiting list group and was stable ($p = 0.79$) for the school group. Therefore, they concluded that fixed appliance orthodontic treatment in adolescents significantly enhanced their aesthetic self-perceptions.

II. Self-concept and self-esteem

The impact of malocclusion and orthodontic treatment on self-concept and self-esteem is a complex area. Adolescents with commonly occurring forms of malocclusion are often presumed to be at risk of developing negative self-esteem and social maladjustment. However, there is limited evidence to support an association between absence of malocclusion and measurably higher self-concept.

These issues will be discussed in greater depth in the systematic review in Chapter II.

Dann *et al.* (1995) measured the self-concept of 208 patients (aged 7 to 15 years) before orthodontic treatment using the Piers-Harris Self-Concept Scale. There was no significant change in the mean self-concept scores during early treatment; nor was there any association between reduction of Class II features and improved self-concept. The authors suggested that children with Class II malocclusions do not generally present for treatment with low self-concept and, on average, self-concept does not improve during the brief period of early orthodontic treatment.

A study conducted by Badran (2010) in Jordan included 385 subjects, aged 14-16 years, who were randomly selected from 12 representative schools located in four areas of Amman. The aims of this study were to evaluate the effect of normative treatment need, perceived treatment need and the influence of self-perceived need and aesthetics on self-esteem. Self-esteem was measured using the Global Negative Self-Evaluation Scale (GSE) and the aesthetic and dental health components (AC and DHC) of the IOTN were used to assess treatment need. The authors concluded that the use of IOTN, especially the AC, reflects subjective treatment need and self-perceived aesthetics. Students who had received orthodontic treatment had higher self-esteem than those who had not undergone treatment and, additionally, dissatisfaction with dental appearance was found to be a predictor for low self-esteem.

Differences have been shown between genders; for example, Jung (2010), showed that following orthodontic treatment there was a significant improvement in self-esteem in adolescent girls, but no significant change was found in boys. In contrast, other studies have reported no significant improvement in self-esteem in relation to orthodontic treatment (Kenealy *et al.*, 2007; Shaw *et al.*, 2007).

The impact of malocclusion and orthodontic treatment on psychological well-being (PWB) and oral-health-related quality of life was assessed by Agou *et al.* (2011) among 11-14 year old children. There were 118 participants in the study (74 in treatment and 44 on the waiting list). Although the treatment patients had significantly better OHRQoL scores at follow-up, the results were significantly modified by individual PWB status ($p < 0.01$). Furthermore, multivariate analysis

showed that PWB contributed significantly to the variance in the Child Perception Questionnaire (CPQ11-14) scores (26%). In contrast, the amount of variance explained by the treatment status alone was relatively small (9%). The results of this study supported the postulated mediator role of PWB when evaluating OHRQoL outcomes in children undergoing orthodontic treatment. It was suggested that children with better PWB were, in general, more likely to report better OHRQoL regardless of their orthodontic treatment status. In contrast, children with low PWB, who did not receive orthodontic treatment, experienced poorer OHRQoL compared with those who received treatment. This suggests that children with low PWB may potentially experience greater benefits from orthodontic treatment.

Environmental effects

I. Social anxiety

Social anxiety is defined as “anxiety that occurs as a result of one’s being concerned about other’s evaluation and perception of him or her” (Leary and Kowalski, 1995). Social Anxiety Disorder (SAD) is defined as “a persistent, lasting 6 months or longer, severe fear that one will do, or say, something embarrassing or humiliating in front of others”; patients who suffer from this condition are afraid that this might expose them to criticism and the anticipation of this evaluation can lead to anxiety and patients frequently avoid social situations (American Psychiatric Association, 2013).

It has been found that physical appearance may be related to social anxiety and a study of individuals who perceived themselves as being unattractive found that they had greater levels of social anxiety (Leary and Kowalski, 1995). However, it remains unclear whether treatment for such conditions improves, worsens or makes no difference to the social anxiety and whether any psychosocial benefit is incurred is uncertain.

Research regarding the effects of malocclusion and orthodontic treatment on social anxiety is still lacking and the relationship between them has not been reported extensively. A positive relationship has been demonstrated between interpersonal relationships and physical attractiveness and negative social feedback associated with less attractive and visible forms of malocclusion is evident. This may be further affected by how those patients with malocclusion interact with new peers and how society perceives their dentofacial disfigurement. It has been suggested that

adolescents with minor forms of facial disfigurement are those who may actually be at greater risk of developing psychological problems because the reaction to them is unpredictable, compared with those who have more severe problems. These patients may then develop anxiety due to this inconsistent behaviour of others (La Greca and Lopez, 1998; Claudino and Traebert, 2013).

Adolescents with malocclusions may face social anxiety, difficulties in relationships with peers, depression, and loneliness (Claudino and Traebert, 2013) and malocclusion has the potential to influence self-perceived appearance, especially during adolescence when there is intense social interaction. Malocclusion may also impair quality of life by affecting function, appearance, interpersonal relationships, socializing, self-esteem and psychological well-being (La Greca and Harrison, 2005; Masood *et al.*, 2013).

Researchers have investigated the effects of orthodontic treatment on social anxiety and psychosocial functioning. A significantly more positive assessment of their appearance was reported post-treatment, with lower levels of anxiety. However, studies have often failed to measure pre-treatment levels of anxiety so there is no pre-treatment comparison. It is therefore not possible to say whether the effect was due to treatment or due to differences in sampling (La Greca and Harrison, 2005; Claudino and Traebert, 2013).

Recently, a cross-sectional study of social anxiety was undertaken in the Orthodontic Department at the UCL Eastman Dental Institute, the study included pre and post-treatment orthodontic patients and a control group of school children who were not having/had not undergone any orthodontic treatment (Read, 2013). The author found no significant difference in social anxiety scores between the pre-orthodontic, post-orthodontic and school groups; the post-orthodontic group had lower scores than the pre-orthodontic group, but this was not significant. Read (2013) did, however, find that females had statistically significantly higher level of fear of negative evaluation (FNE) in comparison with males ($p=0.002$).

II. Social interactions

Social interactions refer to “particular forms of externalities, in which the actions of a reference group affect an individual's preferences”. The reference group is usually an individual's family, neighbours or friends (Jose, 2008). The opportunity for social

interactions helps children and adolescents to develop a sense of “self” and this is considered vital to mental and physical health (Changnon, 2013).

It is evident that facial attractiveness and aesthetics play a central role during the developmental stages in an individual's personal and social life (Albino *et al.*, 1994). There is a strong correlation between facial appearance and social attractiveness and, for young people, physical attractiveness is an important factor affecting social relationships. Adolescence is an important period when individuals start to widen their social network and make confidential and intimate friendships (La Greca and Harrison, 2005). However, they may face difficulties in relationship with peers related to psychological problems, including depression, loneliness and limited social interaction (Claudino and Traebert, 2013).

Adolescents with malocclusions are often presumed to be at risk of social maladjustment and it is possible that certain occlusal traits might have a more negative impact than others on social interactions. Kerosuo *et al.* (1995) conducted a study to assess the importance of dentofacial appearance on the perceived social attractiveness of young adults in Finland, this study was a modification of a method developed by Shaw *et al.* (1985). Facial photographs of 6 young adults were modified so that each face had one of four dental arrangements: incisor crowding, a median diastema, protruding incisors and an ideal anterior occlusion. A sample of 1,007 Finnish students was asked to complete a questionnaire making judgments according to the dentofacial appearance. The authors found that dental arrangement had a significant effect ($p < 0.001$) on the perceived attractiveness and the perceived success of the individual in the photograph. Test faces with incisor crowding and a median diastema were ranked as significantly less intelligent, beautiful and assumed to belong to a lower social class than those faces with an ideal occlusion or protruding incisors. They concluded that incisor crowding and spacing represented a social disadvantage compared with a normal occlusion or protruding incisors. It must, however, be noted that this study was undertaken more than 20 years ago and it is possible that societal norms have changed further since that time.

The psychological and social effects of orthodontic treatment were studied by Albino *et al.* (1994) in a randomized controlled study with 93 participants, who were 11 to 14 years old. Parent, peer, and self-evaluations of dentofacial attractiveness

significantly improved after orthodontic treatment, but treatment did not affect parent- and self-reported social competency or social goals, nor the subjects' self-esteem. In summary, dental-specific evaluations appeared to be influenced by treatment, whilst more general psychosocial responses were not.

III. School interactions

Body image plays an important role in psychological, social adjustment and educational success in children and adolescents (de Paula *et al.*, 2009). Positive social relationships with peers in childhood have been associated with academic success and interpersonal harmony later in life, while poor social relations in childhood have been linked to academic difficulties and mental health problems (La Greca *et al.*, 1988).

Bullying is endemic among schoolchildren with a reported prevalence ranging from 5% to 58% worldwide (DiBiase and Sandler, 2001) and much of the bullying which occurs is in a school setting hence its inclusion in this section. Bullying has been described as “a situation in which a person is exposed repeatedly and over time to negative actions by at least one person”. Negative actions can be classified as direct (hitting, kicking, insults, and threats) or indirect (gossip, spreading of rumors, and social exclusion) forms of aggression that cause harm to the victim. The effects of bullying can be devastating and long lasting. The persistently bullied child appears to represent a certain psychological type, with poorly developed social skills and a submissive nature. Physical appearance, including facial and dental appearance, does seem to play a role, although these tend not to be primary factors (DiBiase and Sandler, 2001).

Seehra *et al.* (2011b) reported that the prevalence of bullying in adolescents with malocclusion referred to their clinic was 12.8% and specific types of malocclusions showed a significant association with bullying, including Class II Division 1 incisor relationship, increased overjet and increased overbite. The authors also investigated the relationship between bullying, malocclusion and its effects on OHRQoL. The bullied participants showed lower levels of self-esteem than non-bullied participants and a negative effect on OHRQoL was reported. A subsequent study by Seehra *et al.* (2013) evaluated patients with a bullying history who underwent early orthodontic treatment and they assessed the effects on their self-esteem and OHRQoL. Thirty-four patients with malocclusions were invited to participate in a longitudinal study

and the participants completed the Olweus Bully/Victim questionnaire, Harter's Self Perception Profile for Children and the Child Perception Questionnaire. The results found that, after starting orthodontic treatment, 21 patients (78%) were no longer being bullied due to their malocclusion. Additionally, in comparison with the T1 score, there were fewer functional limitations ($p=0.013$), reduced emotional effects ($p<0.001$) and less social impact ($p<0.001$). There was improved overall oral health ($P=0.03$) and OHRQoL ($P=0.013$). However, the study reported no significant effect on self-esteem. The authors concluded that orthodontic treatment may have a positive impact on adolescents with a bullying history due to their malocclusion.

There is overlap between bullying and teasing and teasing is, in fact, a form of bullying. Shaw *et al.* (1980b) reported that teeth represented the fourth most common target of teasing for children aged 9 to 12 years, after height, weight, and hair. Teasing due to malocclusion is thought to result in both physiological and psychological symptoms (Korabik, 1994). Both males and females are subjected to teasing and its prevalence in the UK among 11 to 12 year old school children is thought to be around 15% (Boulton and Underwood, 1992). Furthermore, children with a malocclusion may be subjected to persistent peer victimisation, resulting in a negative impact on oral health-related quality of life (OHQoL) (Seehra *et al.*, 2013).

Summary of psycho-social measures

In orthodontics, many of the traditional orthodontic measures and indices are based on objective ways of prioritizing and evaluating orthodontic treatment need and outcome. More recently, the importance of the patient's own opinions has been recognised and a number of studies investigating the effects of malocclusion and orthodontic treatment on psycho-social well-being have been published.

A variety of instruments have been used to measure QoL or more specific psycho-social elements (for example, self-concept, self-esteem, social anxiety, etc). However, there are relatively few questionnaires which have been developed specifically for orthodontics (Mandall *et al.*, 1999; Benson *et al.*, 2016; Patel *et al.*, 2016).

Experts in social research suggest the use of both generic and condition specific questionnaires. However, there are a few condition specific questionnaires available

for the profession. This means that research in orthodontics has often used generic questionnaires rather than condition specific questionnaires and these have frequently not been developed with similar populations. For example, the Child Perceptions Questionnaire (CPQ 11-14) has been utilised but was not developed specifically for orthodontics (Jokovic *et al.*, 2002). Likewise, the Oral Health Impact Profile (OHIP) has been used in a number of studies but was originally developed for use with a much older general dental cohort (Slade and Spencer, 1994). These measures therefore clearly have limitations. It is only very recently, that a condition specific quality of life measure (the Malocclusion Impact Questionnaire [MIQ]) has been developed specifically for orthodontic patients (Benson *et al.*, 2016; Patel *et al.*, 2016). It is important that questionnaires are developed specifically for this cohort in order to enrich research into quality of life and psycho-social well-being.

Summary of the chapter

Overall, it is clear that the relationship between malocclusion, orthodontic treatment and psychosocial well-being is complex. Therefore, the role of the family and the clinician in identifying if there are any psycho-social risk factors affecting the child is important; this might help to identify a problem and provide early intervention, thus reducing the risk of unwanted psycho-social problems at a later stage.

Despite the conflicting evidence regarding the physical (oral health and function) and psycho-social (internal and environmental) effects of malocclusion and orthodontic treatment, there is general acceptance that patients are motivated to seek orthodontic treatment because of these effects. Therefore, there is a need for a greater understanding of the various effects of malocclusion and the benefits of orthodontic treatment.

Assessing the effects of malocclusion and orthodontic treatment on quality of life is important as the number of patients requesting treatment increases year-on-year; there is a need to evaluate their expectations and the possible outcomes of treatment. Furthermore, there is an increased demand to justify the need for, and benefits of, orthodontic treatment for oral health care providers, health planners and researchers. Therefore, instruments assessing OHRQoL, social and psychological factors are important to include alongside clinical assessment tools in orthodontics.

Summary of the research

The aim of this PhD was to explore the psycho-social and QoL impacts of malocclusion and orthodontic treatment in adolescent patients. The following section presents a summary of the research and the reasons why specific areas were investigated.

The first section of the PhD was a systematic review of the literature to investigate the quality of life and psycho-social changes associated with orthodontic treatment. In addition, the strength and weakness of evidence in this area were highlighted in order to determine whether orthodontic treatment had any impacts on psycho-social and QoL aspects.

From discussion with experts in the field during the preparation for this research, it was evident that there are a growing number of experts who believe that the changes experienced as a result of orthodontic treatment are more likely to be social effects than actual psychological effects. Therefore, a decision was made to look specifically at social impacts, rather than broader psycho-social and QoL impacts, for the remainder of the PhD.

A longitudinal controlled clinical study was then undertaken to look specifically at social impacts in a group of adolescent orthodontic patients before and after functional appliance treatment for Class II Division 1 malocclusions and the findings were compared with a control group of orthodontic patients of the same age range who were not undergoing any treatment.

Assessing elements such as social impact can be difficult utilising traditional quantitative methodologies, so the final chapter was a qualitative study undertaken to investigate social impacts of malocclusion as it was felt important to explore this area in more detail.

The three studies together, and the different methodologies used, allowed a more in-depth exploration of social impacts of malocclusion and orthodontics in our patients.

Chapter II: Systematic review of psychosocial and quality of life impacts of orthodontic treatment in children and adolescents

2.1 Introduction

The psycho-social and quality of life impacts of malocclusion and orthodontic treatment in adolescent patients are unclear. As discussed earlier in the literature review, there remains disagreement regarding whether or not there are any significant effects and this inevitably affects research in this field.

Conflict arises when views are expressed about the impacts of different types and severity of malocclusions on self-concept, self-esteem and social anxiety. It is reasonable to assume that untreated malocclusions may have psycho-social and QoL effects and there is now evidence in the literature to suggest that this is the case. However, the evidence looking at the effects of orthodontic treatment are more controversial and this was, therefore, the focus of this systematic review.

2.2 Methods

The initial search was undertaken in September 2013 and included papers from 1980 to 2013. The search was then updated in September 2015 and included papers published between September 2013 and September 2015.

2.2.1 Aim of the systematic review

To evaluate the social, psychological and quality of life changes associated with orthodontic treatment in children and adolescents.

2.2.2 Conducting the systematic review of the literature

Focused question

The focused question for this systematic review was: In children and adolescents with malocclusions, what are the psycho-social effects and the effects on quality of life associated with orthodontic intervention?

Criteria for considering studies for this review

Types of studies

- Randomised Controlled Trials (RCTs): active orthodontic treatment compared with a control group (no treatment, delayed treatment or different types of treatment).
- Observational studies, including: retrospective or prospective studies; case series, case control, cohort, cross-sectional and longitudinal studies: active orthodontic treatment only.

Types of participants

Table 1 illustrates the inclusion and exclusion criteria for patients in the studies included in this review.

Inclusion/exclusion criteria	
Inclusion criteria	Exclusion criteria
Males and/or females	Craniofacial syndromes
Children and/or adolescents	Cleft lip and/or palate
Age range from 7 to 16 years old at the commencement of orthodontic treatment	Individuals with a history of facial fractures due to trauma
	Individuals undergoing orthognathic treatment

Table 1: Inclusion/exclusion criteria for the systematic review

Type of interventions

Active interventions groups:

Orthodontic appliances to treat different forms of malocclusion in adolescents, including:

Removable appliances
Fixed appliances
Functional appliances
Headgear (conventional or protraction facemask)
Any combination of these reported in the literature

Control groups:

No treatment
Delayed treatment
Different types of treatment

Types of outcome measure

Primary outcome:

The social, psychological and/or QoL effects following orthodontic treatment.

2.2.3 Search methods for identification of studies

Electronic searches

For the identification of studies included or considered for inclusion in this systematic review, detailed search strategies with search filters were developed for each database to be searched (from 1980 to present). The starting point of 1980 was chosen as it allowed for the effects of contemporary orthodontics to be assessed and because the majority of the psycho-social literature in the field of orthodontics is after that time. The search was based on the search strategy developed for MEDLINE via Ovid but revised for each database to take account of differences in controlled vocabulary and syntax rules (Appendix 1). The subject search used a combination of controlled vocabulary and free text terms.

To design the search strategy the following steps were taken:

1. The databases to be searched were established:
 - MEDLINE via Ovid (Online database of health, medical journals and other news sources)
 - PsycINFO (Online database of psychological literature)
 - Web of Science (Online multidisciplinary database covering all sciences)

- Embase (Online database of health and medical journals)
 - Cochrane Library
 - LILACS (Online database on health sciences, published in Latin America and Caribbean)
2. The topic and the research question were discussed in detail with all members of the research team and brainstorming of keywords was undertaken. All of the synonyms or related terms and alternative spellings (British versus American spelling) were also determined and included if appropriate.
 3. Mesh terms and free-text terms were determined. It was also confirmed which free-text terms used features such as truncation or wildcard symbols (?, *, !, \$) in order to look for variations in words. Each database used different truncation symbols.
 4. Variations between databases were checked within the instruction home page, titled “Help”, “Frequently Asked Questions”, etc.
 5. Each of the databases uses different Mesh-terms, so it was important to ensure that all terms were included in the different databases. These were added as free-text to other databases.
 6. All Mesh-terms were reviewed to ensure no repetition within them. For example: in the Web of Science database, body image was included within the “perception” mesh-term, so body image was not included as a mesh-term also.
 7. The search was refined to the specific age group (children and adolescents) and dates.
 8. A search filter was then applied to identify randomised controlled trials and observational studies in the different databases (Table 2).

The database	The search filter	
	Randomised Controlled Trials	Observational studies
MEDLINE via Ovid	Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011)	Developed in-house by SIGN (The Scottish Intercollegiate Guidelines Network, 2013)
PsycINFO	Eady <i>et al.</i> (2008)	National Collaborating Centre for Mental Health (2011)
Web of Science	Tjosvold (2013)	Developed by the researcher of this study
Embase	Developed in-house by SIGN (The Scottish Intercollegiate Guidelines Network, 2013)	Developed in-house by SIGN (The Scottish Intercollegiate Guidelines Network, 2013)
Cochrane Library	---	---
LILACS	---	---

Table 2: Sources of the search filters

9. Terms were combined using connectors (Boolean logic), including AND and OR to allow combinations of words.
10. The search strategy was saved.
11. An alarm was created to ensure the researcher (HMA) was emailed when there were new articles published which matched the search.
12. Different databases with different strategies were searched.

The search strategy was reviewed on a number of occasions until the researchers were satisfied that it was comprehensive and appropriate and the search was then the search was performed and exported to Endnote 16. Duplicates were identified and removed.

Manual searches

No manual search was performed because it was felt that searching six databases was likely to identify the majority of articles and that the time spent on hand searching was unlikely to be of significant additional benefit.

Obtaining additional information and searching other resources

Authors of relevant studies were contacted for clarification of any information that was unclear in included papers. The reference lists of all included papers were also checked for additional studies.

Language

The search was designed to identify all relevant studies with no language restrictions. Every attempt was made to translate non-English papers.

2.2.4 Methods of review

Data collection and analysis

All eligibility decisions were performed by 2 researchers (HMA and SJC) as this reduced the chances of relevant papers being excluded inappropriately. Both researchers independently selected studies, extracted data and assessed the risk of bias in the included studies. The data was collected in two cohorts; from 1980 to September 2013 and then the search was updated for the period between September 2013 and September 2015.

Study selection

Stage 1: Selection of abstracts

Selection of abstracts to be included was undertaken by assessing the titles and the abstracts themselves. The reviewers independently confirmed whether or not each abstract met the predetermined eligibility criteria. At the first stage, if the abstract definitely failed to meet the inclusion criteria, it was rejected. If the abstract showed any doubt, the full text was obtained. Agreement was assessed using the Kappa statistic as defined in the Cochrane Handbook (Higgins and Green, 2011). The Kappa statistic was calculated using GraphPad software

(<http://www.graphpad.com/quickcalcs/kappa1/>). Disagreement between the reviewers was resolved by discussion.

Stage 2: Data extraction sheet development (Appendix 2)

The data extraction sheet was developed specifically for this study and included the following: a section at the beginning to assess study eligibility and in order to determine whether the studies to be tested met the inclusion criteria. If the study did not meet the criteria, then it was excluded at this stage. Otherwise the study was included and data was collected regarding:

- Study characteristics: type of study, aims, sample size calculation, setting, ethical approval, funding,
- Participants: number of participants (patients and controls), age, gender, ethnicity, type of malocclusion, informed consent
- Treatment description: type and duration of treatment, duration of follow-up
- Outcome measures: as it was anticipated that this would most frequently be questionnaires, the most commonly used questionnaires were listed in a tick box format, with an “other” section for less commonly used instruments.
- Results: results for each questionnaire were recorded in detail
- Quality assessment: quality assessment and risk of bias were recorded

All data was recorded in table format; this allowed information to be added as appropriate. A tick box format was included where possible for ease of use. Data was collected independently by the two review authors (HMA and SJC).

The data extraction sheet was pilot tested on a sample of eight papers, including some thought to be definitely eligible, some perceived to be definitely not eligible and others which were questionable. The pilot study was used to refine the data extraction sheet, whilst training the reviewers and ensuring that the criteria could be applied consistently.

Stage 3: Data extraction and management

Full text evaluation

The next stage of study selection involved reading the full text to assess the eligibility for inclusion and the Kappa statistic was calculated for inter-examiner agreement. Data was extracted using the data collection sheet described above.

Stage 4: Risk of bias and quality assessment

To be able to assess the quality of the included studies, quality assessment of each individual paper was undertaken.

Quality assessment for Randomised Controlled Trials

Quality assessment of each study is important to identify potential areas of bias, allow comparisons and aid interpretation of findings. The two review authors (HMA and SJC) independently assessed the risk of bias for RCTs according to the Cochrane Collaboration tool for assessing risk of bias as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). The gradings were compared and any inconsistencies in the assessments between the reviewers were discussed and resolved. The two-part tool, addressing different sources of bias (selection, performance, detection, attrition, reporting and other biases), was used for all RCTs (Appendix 3).

Quality assessment for the observational studies

The Newcastle Ottawa Scale (NOS) is one of the quality assessment tools recommended by the Cochrane Collaboration to assess the quality of non-randomised studies (http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm). This scale was initially piloted for a number of included studies, however, there were marked limitations in its use with the studies included in this systematic review. Therefore, it was decided to modify the scale specifically for this study. The modifications better suited the research question and the types of studies included (Appendix 4).

The Newcastle Ottawa scale was modified based on the following main sections of the scale:

1. *Selection bias*: it was important to assess the level of bias in selection of participants, according to the inclusion/exclusion criteria in this review. Clarifications were made to the scale to assist the reviewers in this assessment.
2. *Comparability*: In orthodontic studies, age and gender are important factors. Therefore, age was selected as the most important factor for assessment of comparability and gender was selected as the second factor.
3. *Outcome*: A question regarding the validity of the outcome measure was added to the modified scale because it was felt important to use a validated measure. Additionally, it was felt that there should be an adequate follow-up period for the outcome of interest and this was specified as at least 6 months post-debond. The number of patients lost to follow-up was also set at < 20% for a study to be given a star rating for that question.

Once the scale had been modified, it was important to determine the cut off for low/high risk of bias. A star was given to identify “high” quality elements of a study and a study was evaluated as having a low risk of bias if it was awarded 9 stars or more out of the total 11 stars. Scores below this represented a high risk of bias. The modified scale was then piloted prior to use in the main study.

Quality assessment using the GRADE system

Studies were also assessed for quality according to the GRADE system which is described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). A number of organizations, such as the World Health Organisation and the National Institute for Health and Clinical Excellence have adopted the use of this system.

Underlying methodology	Quality rating
Randomized trials or double-upgraded observational studies	High
Downgraded randomized trials or upgraded observational studies	Moderate
Double-downgraded randomized trials or observational studies	Low
Triple-downgraded randomized trials or downgraded observational studies or case series/ case reports	Very low

Table 3: Levels of quality of evidence in the GRADE system

The GRADE system includes four levels of quality: high, moderate, low and very low (Table 3), with the highest rating given for RCTs. The review authors can downgrade studies to a lower level of quality of evidence and observational studies may also be upgraded depending on a number of factors. Examples of such factors are shown in Table 4.

Factors that might increase the quality level of a body of evidence	Factors that might decrease the quality level of a body of evidence
Large magnitude of effect	Limitations in the design and implementation of available studies suggesting high likelihood of bias, such as: more than 50% loss to follow-up
All plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results show no effect	Indirectness of evidence (indirect population, intervention, control, outcomes)
	Unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses)
	Imprecision of results (wide confidence intervals)
	High probability of publication bias

Table 4: Factors that might increase or decrease the quality level according to the GRADE system

Both researchers assessed the quality of the evidence separately. Where there was a difference in rating between the researchers, the findings were discussed in order to reach an agreed rating.

Dealing with missing data or uncertainty over inclusion of studies

If there was any debate over the inclusion of a study or the data included, the respective author(s) were contacted in an attempt to retrieve the pertinent information.

Assessment of heterogeneity

Studies included in a systematic review will always exhibit differences or heterogeneity. In this study there was sufficient heterogeneity that a meta-analysis was not considered appropriate for the majority of the findings. However, the extent of heterogeneity was still considered in interpretation of the findings of some studies.

Three types of heterogeneity were considered according to the following sub-headings: statistical, clinical and methodological.

- **Statistical**

This may be because of the use of different statistical methods.

- **Clinical**

This may be due to evaluation of different characteristics, treatments or outcomes, such as:

- Participants (age, inclusion and exclusion criteria)

- Malocclusion types

- Interventions

- Time periods

- Different outcomes (such as assessment criteria and psycho-social measures)

- **Methodological/ quality**

This may be due to methodological diversity, such as:

- Type/design of the study

- Randomisation and/or blinding

2.3 Results

2.3.1 Search and screening results:

As described in the methodology, the search was conducted at two time points.

2.3.1.1 Study selection: Initial search (September 2013)

Selection of abstracts

A total of 4,047 abstracts were identified in the initial search for possible inclusion. Those foreign language publications which had an English title and English abstract were assessed in the normal way. If this was not the case, the title and abstract were translated using Google translate ([www. https://translate.google.co.uk](https://translate.google.co.uk)). If there was any doubt over the eligibility for inclusion, the abstract was included and the full text obtained. The final decision was made to include 7 of the foreign language abstracts. Reviewer agreement was calculated using the kappa scores and interpreted based on the scores shown in Table 5.

K	Interpretation
0.40-0.59	Fair agreement
0.60-0.74	Good agreement
0.75 or more	Excellent agreement

Table 5: Kappa statistic values and their interpretation (Streiner *et al.*, 2014)

The kappa value for selection of abstracts was found to be good at **0.736** (95% Confidence Interval: 0.658 to 0.814) (Table 6).

Review author 2 (SJC)	Review author 1 (HMA)				
		Include	Exclude	Unsure	Total
	Include	43	7	3	53
	Exclude	8	3958	11	3977
	Unsure	3	6	8	17
	Total	54	3971	22	4047

Table 6: Inclusion and exclusion of abstracts for the initial search

After further discussion it was agreed to include 70 articles for the second stage of the full text evaluation. Despite duplicates being removed through EndNote 16, it was noted that there were 16 duplicates included and they were removed at this stage. Therefore, 54 articles were included for the next stage (Figure 3).

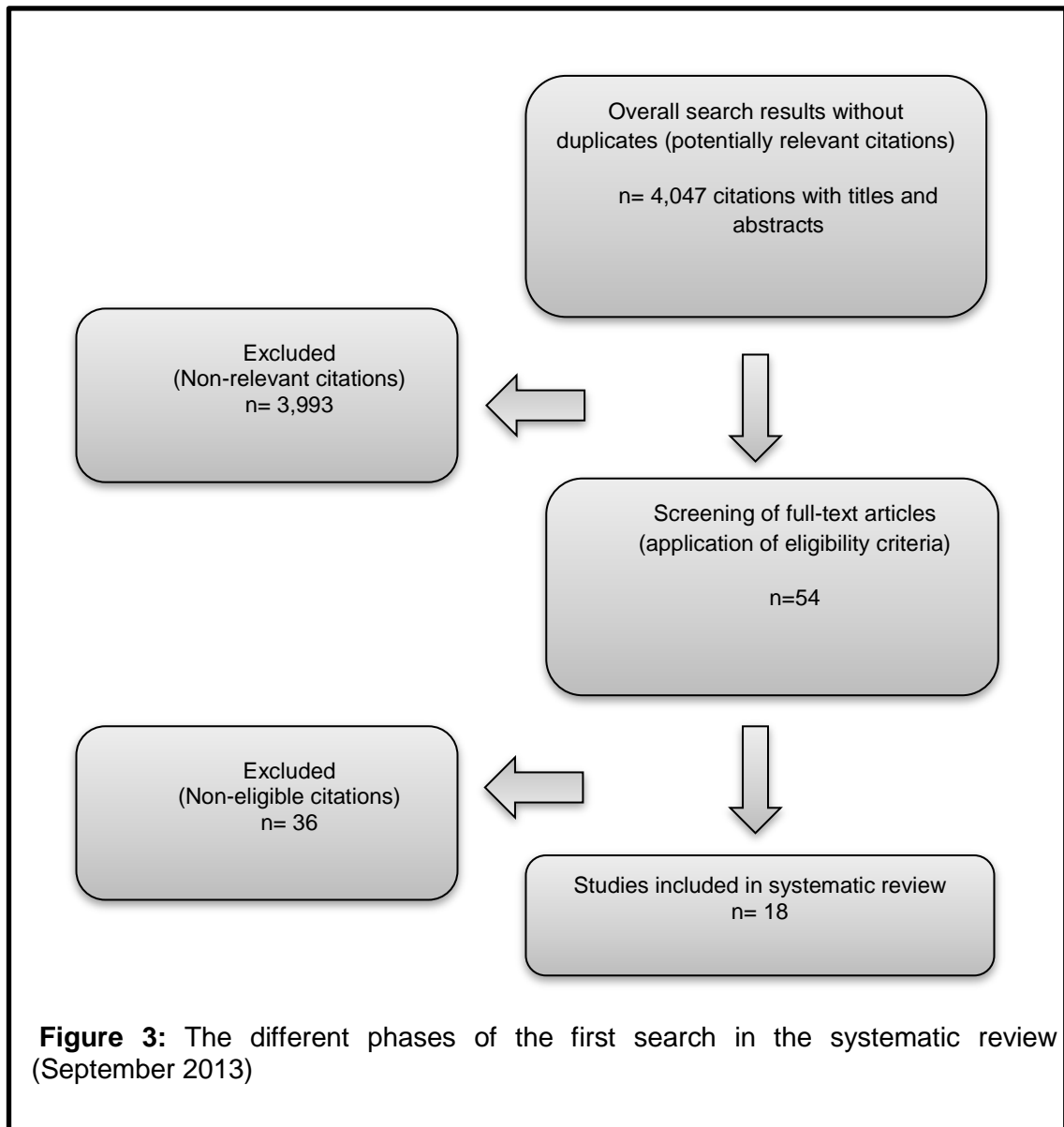
Full text evaluation

Fifty four full-text articles were evaluated for full text inclusion and the reviewer agreement was calculated using kappa scores and found to be excellent at **0.765** (95% Confidence Interval: 0.610 to 0.921) (Table 7).

Review author 2 (SJC)	Review author 1 (HMA)				
		Include	Exclude	Unsure	Total
	Include	18	2	0	20
	Exclude	1	27	1	29
	Unsure	2	1	2	5
	Total	21	30	3	54

Table 7: Inclusion and exclusion of full text papers for the initial search

Thirty articles were excluded during the initial part of the full-text screening because the articles were not relevant to the research question and related to research about the effects of malocclusion on quality of life with no orthodontic intervention, satisfaction with outcomes of orthodontic treatment, or included outcomes or populations outside the inclusion criteria of this review. Details of these studies are included in Table 10. Six articles were provisionally included, but subsequently had to be excluded as there was insufficient data provided in the papers and the authors either failed to respond to the emails requesting further information or the information provided indicated that the papers could not be included (Table 11). At the end of the initial search, 18 articles were therefore included for full-text analysis (Table 10).



2.3.1.2 Study selection: Updated search (September 2015)

Selection of abstracts

The second search was undertaken in September 2015 and used the same search strategy. A total of 756 abstracts were identified for possible inclusion and the reviewer agreement for inclusion was found to be fair with a kappa score of **0.497**

(95% Confidence Interval: 0.150 to 0.845) (Table 8). Where there was doubt regarding inclusion, the abstract was included at this stage.

Review author 2 (SJC)	Review author 1 (HMA)				
		Include	Exclude	Unsure	Total
	Include	2	0	0	2
	Exclude	0	747	5	752
	Unsure	0	1	1	2
	Total	2	748	6	756

Table 8: Inclusion and exclusion of abstracts for the updated search

Full text evaluation

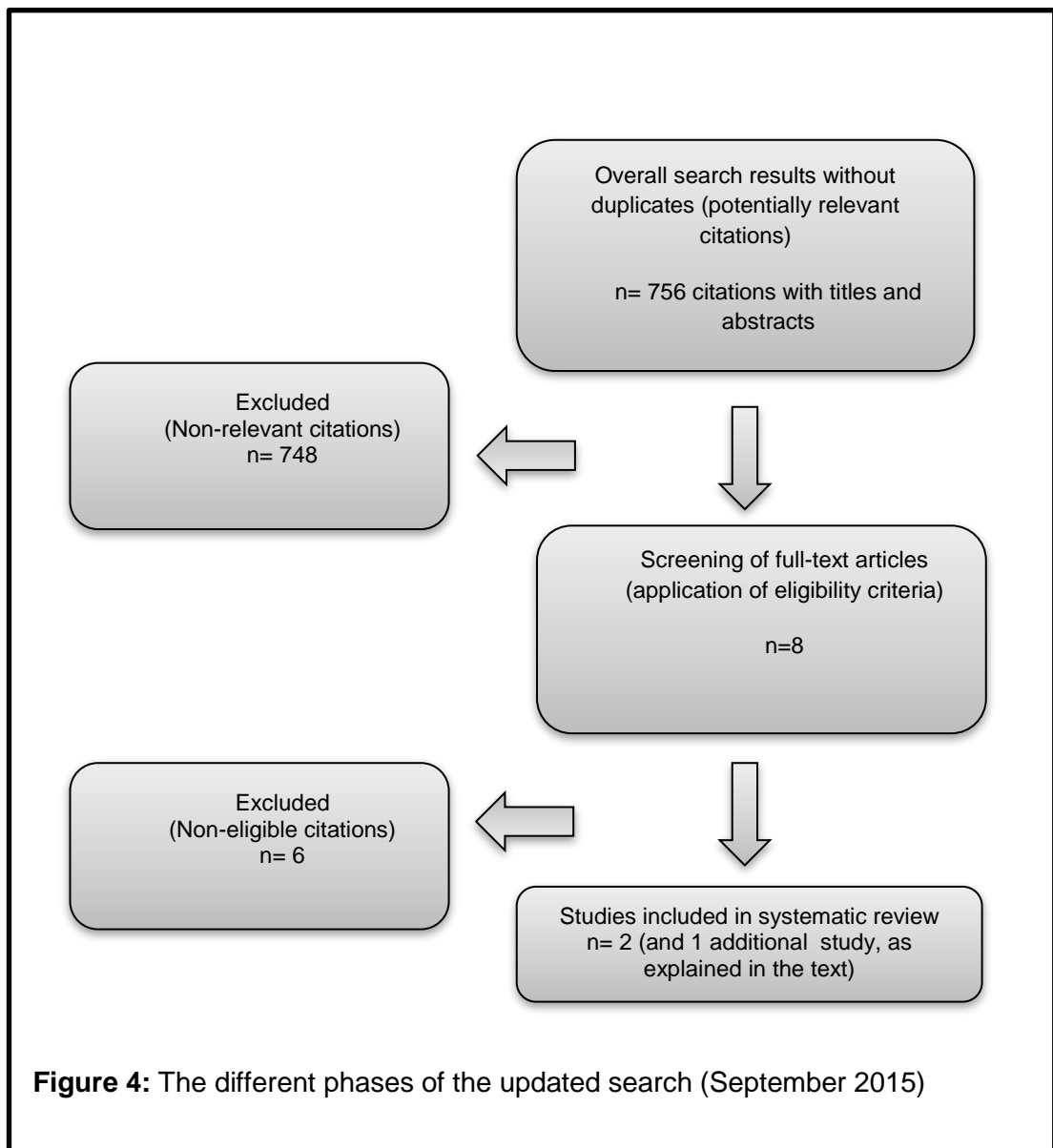
Following exclusion of non-relevant articles, eight articles were obtained for full-text evaluation (Figure 4). Six articles were subsequently excluded during the full-text evaluation because they were not relevant to the research and two articles were included for full-text analysis (Table 9).

The reviewer agreement was found to be fair at **0.500** (95% Confidence Interval: 0.020 to 1.000) (Table 9).

Review author 2 (SJC)	Review author 1 (HMA)				
		Include	Exclude	Unsure	Total
	Include	2	2	0	4
	Exclude	0	4	0	4
	Unsure	0	0	0	0
	Total	2	6	0	8

Table 9: Inclusion and exclusion of full text paper for the updated search

One article has been excluded during the initial search due to receiving no response from the author regarding additional data requested (Badran, 2010). However, based on the advice of an expert in systematic reviews (IN) a decision was subsequently made to include this paper in order to avoid the exclusion of potentially useful information and this paper was therefore also included at this stage.



Overall, a total of 21 articles were included in this systematic review. Several articles reported data from the same study and a description of these articles is included in Table 10.

Table 10: Studies included in the final data extraction

No	Author/s year	Title	Journal	Aims of the study
Publications reporting data from the same study				
1 & 2	de Oliveira and Sheiham (2003)	The relationship between normative orthodontic treatment need and oral health-related quality of life.	Community Dentistry and Oral Epidemiology	1,675 Brazilian adolescents recruited to assess whether a history of orthodontic treatment affected OHRQoL impacts and to assess the relationship between a normative clinical measure of orthodontic treatment need and 2 measures of OHRQoL.
	de Oliveira and Sheiham (2004)	Orthodontic treatment and its impact on oral health-related quality of life in Brazilian adolescents.	Journal of Orthodontics	1,675 Brazilian adolescents randomly selected to study whether adolescents who had completed orthodontic treatment had lower levels of impact on their OHRQoL compared with adolescents under treatment or those who had never had treatment.
3 & 4	Kenealy <i>et al.</i> (2007)	The Cardiff dental study: a 20-year critical evaluation of the psychological health gain from orthodontic treatment.	British Journal of Health Psychology	1,018 participants were initially evaluated in 1981, with assessment of dental health and psychological well-being. An observational approach was performed with no recommendation about orthodontic treatment. After 20 years the participants were re-examined to compare the dental and psychosocial status of those who received, or did not receive, orthodontic treatment as teenagers.
	Shaw <i>et al.</i> (2007)	A 20-year cohort study of health gain from orthodontic treatment: psychological outcome.	American Journal of Orthodontics and Dentofacial Orthopedics	1,018 participants (aged 11 to 12 years) were initially evaluated in 1981. An observational approach was performed with no recommendation about orthodontic treatment. After 20 years the participants were re-examined to compare the dental and psychosocial status of participants who received, or did not receive, orthodontic treatment as teenagers.

Publications reporting data from the same study but at different time points				
5 & 6	O'Brien <i>et al.</i> (2003)	Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 2: Psychosocial effects.	American Journal of Orthodontics and Dentofacial Orthopedics	174 children (aged 8-10 years) randomly allocated to receive early treatment with a Twin-block appliance or to a control group (conventional timing of treatment), the aim being to investigate the effectiveness of early orthodontic treatment for Class II Division 1 malocclusion at 15 months follow-up.
	O'Brien <i>et al.</i> (2009)	Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: a multi-center, randomized, controlled trial.	American Journal of Orthodontics and Dentofacial Orthopedics	174 children (aged 8-10 years) randomly allocated to receive treatment with a Twin-block appliance or to a control group to investigate the effectiveness of early orthodontic treatment for Class II Division 1 malocclusion at 3-year follow-up.
7 & 8	Mandall <i>et al.</i> (2010)	Is early Class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up.	Journal of Orthodontics	73 patients randomly allocated into either an early Class III protraction facemask group or a control (no treatment) group to examine the effectiveness of early Class III treatment at 15 months follow-up.
	Mandall <i>et al.</i> (2012)	Is early Class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 3-year follow-up.	Journal of Orthodontics	73 patients randomly allocated into either an early Class III protraction facemask group or a control (no treatment) group to examine the effectiveness of early Class III treatment at 3-year follow-up.
Publications reporting data in single paper				
9	Albino <i>et al.</i> (1994)	Psychological and social effects of orthodontic treatment.	Journal of Behavioral Medicine	93 adolescents randomly allocated to receive orthodontic treatment or to act as controls (delayed treatment) to study the psychosocial effects of orthodontic treatment.

10	Korabik (1994)	Self-concept changes during orthodontic treatment.	Journal of Applied Social Psychology	81 patients examined for self-concept in association with orthodontic treatment.
11	Dann et al. (1995)	Self-concept, Class II malocclusion, and early treatment.	Angle Orthodontist	208 patients examined to assess whether children with Class II malocclusions have low self-concept and whether early treatment improves self-concept. Some patients were part of a pre-existing RCT and others were recruited from a graduate clinic. 104 patients from the RCT group had full pre and post-treatment data available and were used in the final analysis.
12	Birkeland et al. (2000)	Relationship between occlusion and satisfaction with dental appearance in orthodontically treated and untreated groups. A longitudinal study.	European Journal of Orthodontics	359 children recruited to determine the relationship between occlusion, satisfaction with dental appearance and self-esteem at 11 and 15 years of age. The authors compared treated patients with untreated patients during that time. Perceived treatment effects were also studied.
13	Mandall et al. (1999) (NB: Referenced as 2000 in Pubmed, but correct reference for article 1999)	Perceived aesthetic impact of malocclusion and oral self-perceptions in 14-15-year-old Asian and Caucasian children in greater Manchester.	European Journal of Orthodontics	434 adolescents randomly selected from schools to assess the effects of ethnicity, social deprivation and gender on whether orthodontic treatment influences perceived oral aesthetic impacts.
14	Schmidt et al. (2008)	Quality of life in children undergoing orthodontic treatment. A cross sectional study.	Monatsschrift Kinderheilkunde	116 children completed the KINDL questionnaires before treatment and 119 after treatment to measure the impact of orthodontic treatment on QoL. <i>(Translated from German to English by Dr. Dirk Bister)</i>
15	Taylor et al. (2009)	Effects of malocclusion and its treatment on the quality of life of adolescents.	American Journal of Orthodontics and Dentofacial Orthopedics	293 participants recruited to assess whether malocclusion, and its treatment, influences an adolescent's QoL.

16	Jung (2010)	Evaluation of the effects of malocclusion and orthodontic treatment on self-esteem in an adolescent population.	American Journal of Orthodontics and Dentofacial Orthopedics	4,509 school students assessed to evaluate the effects of malocclusion and orthodontic treatment on self-esteem.
17	Agou <i>et al.</i> (2011)	Does psychological well-being influence oral-health-related quality of life reports in children receiving orthodontic treatment?	American Journal of Orthodontics and Dentofacial Orthopedics	118 children participated in a study to determine OHRQoL outcomes following orthodontic treatment, whilst controlling for individual psychological characteristics.
18	Arrow <i>et al.</i> (2011)	Quality of life and psychosocial outcomes after fixed orthodontic treatment: a 17-year observational cohort study.	Community Dentistry and Oral Epidemiology	3,925 children were examined as adolescents and followed up 17 years later. QoL and psychosocial outcomes were measured to study the impact of orthodontic treatment.
19	Badran (2010)	The effect of malocclusion and self-perceived aesthetics on the self-esteem of a sample of Jordanian adolescents.	European Journal of Orthodontics	410 students were examined to evaluate whether having orthodontic treatment affects self-esteem in comparison with others who did not have treatment. The participants answered the Global Negative Self-Evaluation (GSE) scale and the IOTN-AC.
20	Feu <i>et al.</i> (2013)	Effect of orthodontic treatment on Oral Health related Quality of Life.	The Angle Orthodontist	284 children were followed for 2 years: 87 were undergoing treatment with fixed orthodontic appliances, 101 were control waiting for treatment and 96 were a control group of school children. All children answered OHIP-14 at baseline (T1), 1 year later (T2) and 2 years later (T3).
21	Benson <i>et al.</i> (2015)	Relationships between dental appearance, self-esteem, socio-economic status and oral health related quality of life in UK schoolchildren: A 3 year cohort study	European Journal of Orthodontics	374 students were recruited from 7 different schools and surveyed at baseline (T1) and 258 followed up 3 years later (T2). They completed the CPQ11-14 and the CHQ-Child Self-Report Form.

Table 11: Studies which were excluded

No	Authors/year	Title	Journal	Reason for exclusion
Studies which were initially included but later had to be excluded due to inadequate information				
1	Moore <i>et al.</i> (1989)	Vertical and horizontal components of functional appliance therapy.	American Journal of Orthodontics and Dentofacial Orthopedics	Second author (Dr Igel) contacted to request data and additional information. No response received.
2	Al-Omiri and Abu Alhaija (2006)	Factors affecting patient satisfaction after orthodontic treatment.	The Angle Orthodontist	First author contacted to ask if they have separate data for patients age between 13 and 16 years because the mean age of included patients in were 20.7 ± 4.2 years; range 13 to 28 years). No response received.
3	Chen <i>et al.</i> (2010)	Fixed orthodontic appliance therapy and its impact on oral health-related quality of life in Chinese patients.	The Angle Orthodontist	First author contacted to ask the age range of patients included (the mean age was 15.7 years so it was not clear if patients over 16 years were included). No response received.
4	King <i>et al.</i> (2012)	Medicaid and privately financed orthodontic patients have similar occlusal and psychosocial outcomes.	Journal of Public Health Dentistry	First author contacted to ask if additional data was available. The reply stated that all data had been included in the paper and that OHRQoL was not recorded at baseline.
5	Zhou <i>et al.</i> (2014b)	Self-ligating brackets and their impact on oral health related quality of life in Chinese adolescence patients	The Scientific World Journal	First author contacted to request data for those patients 16 years and below (age range included was 13-18 years). No response received.

Studies excluded following full text analysis				
1	Hershon and Giddon (1980)	Determinants of facial profile self-perception.	American Journal of Orthodontics	Outcome of interest not reported.
2	Kenealy <i>et al.</i> (1989)	An evaluation of the psychological and social effects of malocclusion: some implications for dental policy making.	Social Science and Medicine	Looked at the effects of malocclusion not orthodontic treatment.
3	Spencer <i>et al.</i> (1995)	Predictors of fixed orthodontic treatment in 15-year-old adolescents in South Australia.	Community Dentistry and Oral Epidemiology	Did not measure QoL or psychosocial outcomes.
4	Pietila and Pietila (1996)	Dental appearance and orthodontic services assessed by 15-16-year-old adolescents in eastern Finland.	Community Dental Health	Looked at satisfaction with dental appearance only.
5	Angermann and Berg (1999)	Evaluation of orthodontic treatment success in patients with pronounced Angle Class III.	Journal of Orofacial Orthopedics	Looked at patient satisfaction with dental aesthetics. The age of the patients was also unclear.
6	Birkeland <i>et al.</i> (1999)	Factors influencing the decision about orthodontic treatment. A longitudinal study among 11- and 15-year-olds and their parents.	Journal of Orofacial Orthopedics	Looked at satisfaction with the dentition.
7	Fernandes <i>et al.</i> (1999a)	Patient-centered evaluation of orthodontic care: A longitudinal cohort study of children's and parents' attitudes.	American Journal of Orthodontics and Dentofacial Orthopedics	Looked at patient/parent satisfaction with dental alignment and desire for orthodontic treatment.

8	Fernandes <i>et al.</i> (1999b)	The provision and outcome of orthodontic services in a Norwegian community: a longitudinal cohort study.	Community Dentistry and Oral Epidemiology	Looked at patient/parent satisfaction with dental alignment and desire for orthodontic treatment.
9	Egermark <i>et al.</i> (2005)	A prospective long-term study of signs and symptoms of temporomandibular disorders in patients who received orthodontic treatment in childhood.	The Angle Orthodontist	Looked at the effect of orthodontic treatment performed in childhood on the long-term development of TMDs rather than QoL.
10	Larsson and Bergstrom (2005)	Adolescents' perception of the quality of orthodontic treatment.	Scandinavian Journal of Caring Sciences	Included patients over 17 years and looked at the quality of care rather than quality of life.
11	Al-Omiri and Abu Alhaija (2006)	Factors affecting patient satisfaction after orthodontic treatment.	The Angle Orthodontist	Included patients over 16 years and measured satisfaction with outcomes.
12	O'Brien (2006)	Is early treatment for Class II malocclusion effective? Results from a randomised controlled trial.	American Journal of Orthodontics and Dentofacial Orthopedics	Summary of a presentation at a symposium and the data was already included in other papers which were analysed for this review.
13	Musich and Busch (2007)	Early orthodontic treatment: current clinical perspectives.	Alpha Omegan	Did not study any psycho-social or QoL impacts due to orthodontic treatment.
14	Mandall <i>et al.</i> (2008)	Prediction of compliance and completion of orthodontic treatment: are quality of life measures important?	European Journal of Orthodontics	Looked at patients aged 10-19 years at the start of treatment and measured patient co-operation during orthodontic treatment.
15	Maia <i>et al.</i> (2010)	Factors associated with long-term patient satisfaction.	The Angle Orthodontist	Included patients over 16 years and looked at satisfaction with the dentition rather than QoL.

16	Bekes <i>et al.</i> (2011)	The German version of the child perceptions questionnaire on oral health-related quality of life (CPQ-G11-14): population-based norm values.	Journal of Orofacial Orthopedics	The patients included in the study were still undergoing treatment, so there was no post-treatment data reported.
17	Hirvinen <i>et al.</i> (2012)	The objective and subjective outcome of orthodontic care in one municipal health centre.	Acta Odontologica Scandinavica	Looked at satisfaction with dental appearance and function.
18	McKeta <i>et al.</i> (2012)	Practitioner and patient perceptions of orthodontic treatment: is the patient always right?	Journal of Esthetic & Restorative Dentistry	Looked at a wide age range (12-40 years) and satisfaction was studied rather than QoL or psychosocial outcomes.
19	Millett <i>et al.</i> (2012)	Treatment and stability of Class II Division 2 malocclusion in children and adolescents: A systematic review.	American Journal of Orthodontics and Dentofacial Orthopedics	This was a systematic review and the inclusion criteria included psychosocial and QoL impacts of orthodontic treatment but no publications were identified in this area.
20	Harrison <i>et al.</i> (2007)	Orthodontic treatment for prominent upper front teeth in children.	Cochrane Database of Systematic Reviews	This was a systematic review but did not include any psycho-social or QoL effects related to orthodontic treatment.
21	Gunenkova (2005)	Orthodontic service as one of the factors of improving quality of life.	Stomatology	There were no data about psycho-social outcomes or quality of life, the paper was concerned with the quality of orthodontic treatment.
22	Duterloo (1998)	Complications in the treatment of angle Class II division 1 malocclusion.	Dutch Journal of Dentistry	Looked at psychosocial complications during orthodontic treatment.

23	Díaz and Curtes (2005)	Effects of orthodontic treatment on body image and self-esteem of adolescents. Final reports.	Rev. Fac. Odontol. Univ. Antioq ♦	No data was reported.
24	Davis <i>et al.</i> (1986)	Effects of orthodontic treatment on adolescent psychosocial characteristics.	Journal of Dental Research	Could not access the full-text article and the EDI librarians contacted a number of libraries, with no success. Only the abstract was available. From the abstract, it was clear that this paper was similar to Albino <i>et al.</i> (1994) study and quoted identical data to that which had already been included.
25	Carrero Martínez <i>et al.</i> (2003)	Self-concept of orthodontic patients to start orthodontic treatment.	Univ. Odontol ♦	Could not access the full-text article and the EDI librarians contacted a number of libraries, with no success.
26	Alves (1996)	A remodelação da auto-estima e estética facial associadas à movimentação ortodôntica e funcional ♦.	Jornal Brasileiro de Ortodontia e Ortopedia Maxilar ♦	Could not access the full-text article and the EDI librarians contacted a number of libraries, with no success.
27	Kenealy <i>et al.</i> (1990)	Psychological benefits of orthodontic treatment.	Nursing Times	Duplicate report- no additional data.
28	O'Regan <i>et al.</i> (1991)	Self-esteem and aesthetics.	British Journal of Orthodontics	Included participants over 16 years.

29	Kenealy <i>et al.</i> (1991)	The psychological benefit of orthodontic treatment. Its relevance to dental health education.	New York State Dental Journal	Duplicate report and no data provided.
<p>◇ Translation according to Google translate, attempts were made to obtain a full text translation but without success. Also, it was unable to find an accurate citation to include them in the list of references.</p> <p>◆ Unable to obtain reasonable translation from Google translate - appears to relate to aesthetic facial changes following functional orthodontic treatment.</p> <p>NB: A paper by Bernabé <i>et al.</i> (2008) was identified subsequent to the second search. Discussion with the second author revealed that the same data was the same as that in de Oliveira and Sheiham (2003; 2004) study, so a decision was made not to include it at that late stage.</p>				

2.3.2 Descriptive results:

In this systematic review, there were 21 publications from 17 studies. To simplify the results and discussion, the number of studies will be referred to rather than number of publications.

2.3.2.1 Study characteristics (Table 12):

- **Study design and Sample characteristics:**

Randomised Controlled Trials (RCTs):

There were four prospective randomised controlled trials included in this review which reported follow-ups ranging from 15 months following the start of treatment (Dann *et al.*, 1995; O'Brien *et al.*, 2003; Mandall *et al.*, 2010) until one year following the completion of all treatment (Albino *et al.*, 1994).

Two studies were in the UK (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) and two in the USA (Albino *et al.*, 1994; Dann *et al.*, 1995). The research sites included hospitals and university clinics; the two British studies were multi-centre studies in orthodontic departments of NHS hospitals and the two American studies were in university clinics.

In three of the RCTs, the treatment group patients had early orthodontic treatment (Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) and the remaining trial involved patients treated at the conventional age between 11 and 14 years (Albino *et al.*, 1994).

Regarding the control groups, in the O'Brien *et al.* (2009) study, this group started treatment at the conventional time after all permanent teeth had erupted (O'Brien *et al.*, 2003; 2009). Mandall *et al.* (2010, 2012) also included a control group who would potentially have orthodontic treatment at a later stage. Albino *et al.* (1994) reported that patients who were not accepted for orthodontic treatment were invited to participate as control participants.

The age at the start of treatment for the treatment groups ranged from an average of 8.7 years (Mandall *et al.*, 2010; 2012) to 12.5 years (Albino *et al.*, 1994), while for the control group the reported age at the start of treatment ranged from an average of 9 years (Mandall *et al.*, 2010; 2012) to 9.8 years (O'Brien *et al.*, 2003; 2009). The study by Albino *et al.* (1994) did not specify the age at recruitment for the control group, but it would appear to be as in the treatment group (12.5 years).

The number of participants ranged from 73 in the Mandall *et al.* study (2010; 2012) to 176 in the O'Brien *et al.* study (2003; 2009). In the Albino *et al.* (1994) study, there were 93 patients at the start of treatment and in the Dann *et al.* (1995) study; there were 104 patients. The gender of the participants was reported in all studies except Dann *et al.* (1995). The ethnicity of the participants was not specified in the O'Brien *et al.* (2003; 2009) study, while the other three studies specified ethnicity. Two studies reported that the participants were Caucasian (Dann *et al.*, 1995; Mandall *et al.*, 2010; 2012) and one study specified that 83 participants were Caucasian and 10 participants were non-Caucasian (Albino *et al.*, 1994).

Observational studies:

There were thirteen observational studies included in the review, of both cross-sectional and longitudinal design. All of the observational studies were prospective.

Three studies were performed in the UK (Mandall *et al.*, 1999; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Benson *et al.*, 2015), two in Canada (Korabik, 1994; Agou *et al.*, 2011), two in Brazil (de Oliveira and Sheiham, 2003; 2004; Feu *et al.*, 2013) and one in Norway, Germany, USA, Korea, Australia and Jordan (Birkeland *et al.*, 2000; Schmidt *et al.*, 2008; Taylor *et al.*, 2009; Badran, 2010; Jung, 2010; Arrow *et al.*, 2011). The settings where the studies were undertaken included schools, university clinics, and community practices.

There were seven longitudinal studies (Korabik, 1994; Birkeland *et al.*, 2000; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Agou *et al.*, 2011; Arrow *et al.*, 2011; Feu *et al.*, 2013; Benson *et al.*, 2015) and the length of follow-up varied between an average of 9.6 months after treatment (Korabik, 1994) to 20 years after initial examination (Kenealy *et al.*, 2007; Shaw *et al.*, 2007).

These longitudinal studies were considered as “before and after treatment” studies and had both treatment and non-treatment control groups. All studies were prospective. The recruitment of those in the treatment and control groups varied between studies. Kenealy *et al.* (2007) and Shaw *et al.* (2007) undertook a 20-year observational study following a cohort of children in Wales and assessed whether there were any differences between participants who had undergone orthodontic treatment and those who had no treatment (considered as a control group) relative to whether they were recorded as having a need for treatment when they were recruited. Similarly, Arrow *et al.* (2011) undertook a follow-up of adults who underwent orthodontic treatment as adolescents and this 17-year follow-up included a community sample of adults as a control group.

Birkeland *et al.* (2000) recruited a cohort of children when they were 11 years of age and then invited them back for follow-up 4 years later, they were then classified according to whether or not they had undergone treatment and the data analysed accordingly. A similar study design was utilised by Benson *et al.* (2015) who undertook their study in state funded schools and recruited a sample of schoolchildren aged 11-12 years. The children were then followed up 3 years later (T2) and data was analysed according to whether or not they had undergone orthodontic treatment in the interim.

Agou *et al.* (2011) recruited patients seeking orthodontic treatment at the orthodontic clinic at the University of Toronto as a treatment group, while patients who were on the waiting list formed a control group. Feu *et al.* (2013) used a similar methodology in their study and also had a second control group recruited from public schools.

The remaining six studies were classified as cross-sectional (Mandall *et al.*, 1999; de Oliveira and Sheiham, 2003; 2004; Schmidt *et al.*, 2008; Taylor *et al.*, 2009; Badran, 2010; Jung, 2010). Taylor *et al.* (2009) undertook a complex study design which they termed “a cross-sectional design with a longitudinal component”; treatment group participants were classified as: pre-comprehensive orthodontic treatment or post-interceptive orthodontic treatment and their control group included patients from paediatric dental clinics. de Oliveira and Sheiham (2003; 2004) selected a random sample of adolescents from public and private schools and classified them into three groups: treated, under orthodontic treatment at the time or untreated. Jung (2010) also undertook their study in schools and classified students

according to whether they had finished orthodontic treatment, were currently undergoing fixed orthodontic treatment, during or finished removable appliance orthodontic treatment, or had undergone no treatment.

The ages and age ranges of the participants at recruitment varied. In the longitudinal studies, Korabik (1994) recruited participants who were 11-16 years of age and Agou *et al.* (2011) had an age range of 11-14 years. The longitudinal Cardiff study (Kenealy *et al.*, 2007; Shaw *et al.*, 2007) and the Benson *et al.* (2015) study both had a smaller age range of 11-12 years of age; this related primarily to the studies recruiting participants from a single school year. The Norwegian study by Birkeland *et al.* (2000) also recruited participants who were 11 years of age. In the cross-sectional studies, the ages ranged from an average of 10 years (Schmidt *et al.*, 2008) to 15-16 years (de Oliveira and Sheiham, 2003; 2004; Badran, 2010) .

The number of participants in the longitudinal studies ranged from 81 (Korabik, 1994) to 3,925 (Arrow *et al.*, 2011), while in the cross-sectional studies numbers ranged from 235 (Schmidt *et al.*, 2008) to 4,509 (Jung, 2010).

Regarding gender, five out of thirteen studies reported more females than males (Korabik, 1994; Birkeland *et al.*, 2000; de Oliveira and Sheiham, 2003; 2004; Schmidt *et al.*, 2008; Jung, 2010). Only four studies reported ethnicity. One study specified that the participants were Caucasian (Kenealy *et al.*, 2007; Shaw *et al.*, 2007), one study specified that the participants were Asian and Caucasian (Mandall *et al.*, 1999), one reported that 76% of participants were white, but did not specify the ethnicity of the other participants (Agou *et al.*, 2011), and white, Hispanic, black, Asian and “other ethnicities” were included in the study by Taylor *et al.* (2009).

Summary:

Four studies were RCTs and thirteen studies were observational. Follow-up tended to be longer in the observational studies (up to 20 years after initial examination) than in the RCTs, the maximum of which was up to one year after completion of treatment.

The majority of the studies were conducted in the UK, then Canada, USA and Brazil. Where there were treatment and control groups, the participants in the control group either had treatment delayed or remained untreated. There were also variations in

age and the number of the participants included. The ethnicity of the participants varied, but was mainly Caucasian. There was marked variation between the studies regarding participant selection, particularly in the observational studies.

- **Drop-out/loss to follow-up and completion of data collection:**

Randomised Controlled Trials (RCTs):

All of the RCTs reported data regarding loss to follow-up, although many different reasons were reported. For the treatment groups reasons included questionnaires not completed, treatment was not completed, detection of bias due to inconsistent replies in the questionnaires, patients decided to accept their occlusion (Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009), patients moved from the area, and repeated failure to keep appointments (Albino *et al.*, 1994). In one study it was reported that the clinician stopped treatment because a patient failed to cooperate (Mandall *et al.*, 2010; 2012).

For the control groups, reasons for loss to follow-up included refusal to have alginate impressions (Mandall *et al.*, 2010; 2012) and patients sought treatment elsewhere due to delays related to their group assignment (Albino *et al.*, 1994).

The extent of the loss to follow-up varied between the trials. O'Brien *et al.* (2003; 2009) reported that 44 of 176 patients (25%) were lost to follow-up at T2 and 49 at T3 (27.8%). The only predictor of missing data at T2 was the Carstairs' Deprivation Score. The authors performed an intention-to-treat analysis and showed that this loss to follow-up did not appear to affect the outcome. The loss to follow up at T2 was similar in the two groups but at T3 there may have been systematic bias, with more patients lost from the treatment group (n=35) compared with the control group (n=14).

Mandall *et al.* (2012) reported that 4 patients were lost to follow up at T2 and 10 at T3, with equal numbers lost from each group at both time points. The authors showed that there was no statistically significant attrition bias due to this loss to follow-up when the baseline characteristics of the patients remaining in the study were compared with those who were lost to follow-up. It appears that this loss to follow-up was random, rather than having systematic element.

Albino *et al.* (1994) reported that 17 of 91 patients (18.7%) were lost to follow-up, with more participants lost from the control “delayed treatment” group (n=12 compared with n=5 in the treatment group) and it is likely that they may have sought treatment elsewhere.

Dann *et al.* (1995) reported that 17 participants were lost to follow-up, but it is not clear if this was a random or systematic loss. There was no comment on loss to follow-up, but it would appear to be potentially due to incomplete data because the self-concept questionnaire was introduced after the RCT began so data was not available for all participants.

Observational studies:

In the observational studies with a longitudinal element, the loss to follow-up varied and different reasons were given for this. In the treatment groups, reasons for loss to follow-up included: patients moved from the area, declined to continue in the study or agreed to continue but did not attend (Korabik, 1994; Birkeland *et al.*, 2000; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Feu *et al.*, 2013; Benson *et al.*, 2015), and another study stated purely ‘unknown reasons’ (Birkeland *et al.*, 2000). However, for the control group in two of the longitudinal studies, the drop-out was due to some patients seeking care elsewhere or relocating outside the city (Agou *et al.*, 2011; Feu *et al.*, 2013).

The size of loss to follow-up in the longitudinal studies was greater than in the RCTs, particularly in the studies with long follow-up periods. In the Cardiff study, only 332 of 1,018 participants completed the study at 20 years. This was almost 70% loss to follow-up and clearly introduces bias (Kenealy *et al.*, 2007; Shaw *et al.*, 2007). The authors stated that the participants at the end of the study retained the main characteristics of the original sample, however, it appears that there were equal percentages (50%) of males and females at T1, but at T3 there were more females (57%) than males (43%). This may not have been significant however.

Similarly, the Arrow *et al.* (2011) study started with 3,925 participants, but only 632 were followed-up at 17 years (a loss of approximately 85%) and not all of those participants completed the relevant questionnaires. This large loss to follow-up means limited conclusions can be drawn and there is insufficient strength of

evidence to conclude that orthodontic treatment has a positive or negative effect on OHRQoL or self-esteem.

In the Agou *et al.* (2011) study, there were a total of 81 participants lost to follow-up (24 participants from the treatment group and 57 participants from the control/ waiting list group). The authors acknowledged this large percentage loss to follow-up (40.71%) in total, but stated that this did not compromise the comparability of T1 characteristics between treatment and control groups. There could potentially be systematic loss to follow-up and it seems likely that some of the control/ waiting list group may have sought care elsewhere. The Feu *et al.* (2013) study, also had more participants lost from the waiting list groups (n=23), than from the treatment (n=5) or school groups (n=6). As in the Agou *et al.* (2011) study, waiting list patients may have sought treatment elsewhere and this must be considered when interpreting the data. Some studies analysed variables between the original baseline sample and the retained sample (Birkeland *et al.*, 2000; Agou *et al.*, 2011; Arrow *et al.*, 2011). However, with large losses to follow-up, it seems likely there were differences.

Birkeland *et al.* (2000) reported a 17% loss to follow-up after four years, although analysis suggested no statistically significant differences between those lost to follow-up and those who remained in the study. In the Korabik (1994) study there was equal loss to follow-up between the groups. However, there was no analysis or data from which further conclusions could be drawn.

With regard to the studies which were cross-sectional in nature, three studies did not report the percentage response (Schmidt *et al.*, 2008; Taylor *et al.*, 2009; Jung, 2010), although a 100% response was reported in the study by de Oliveira and Sheiham (2004) and a 77% response was reported in the study by Mandall *et al.* (1999).

Summary:

Causes of loss to follow-up were different between the studies and also varied between treatment and control groups. In the treatment groups this was mainly due to moving away, declining to continue in the study and failing appointments, while for the control group, delays in treatment and patients seeking treatment elsewhere were the main reasons. The high percentage loss to follow-up in some studies raises the likelihood of attrition bias, this particularly affected those studies which

followed participants for long periods of time and means that limited conclusions can be drawn.

- **Types of outcomes, Patient and Treatment characteristics:**

Randomised Controlled Trials (RCTs):

At baseline, different types of data were collected, including clinical data, measurements from study models and/or lateral cephalograms and questionnaires. There were a large number of different questionnaires utilised in the studies included in this review but the most commonly used questionnaire in the RCTs was the Piers-Harris Self-Concept Scale; with three studies using this scale (Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012).

Three of the four studies reported the malocclusion types; the malocclusions included Class II unspecified (Dann *et al.*, 1995), Class II Division 1 (O'Brien *et al.*, 2003; 2009) and Class III (Mandall *et al.*, 2010; 2012). However, one study did not report the malocclusions included in their study (Albino *et al.*, 1994).

All of the RCTs reported the type of orthodontic treatment; one study used functional appliances or headgear (Dann *et al.*, 1995), one study used the Clark Twin-block functional appliance and fixed appliances (O'Brien *et al.*, 2003; 2009), one study used protraction headgear with rapid maxillary expansion (Mandall *et al.*, 2010; 2012) and one used a variety of orthodontic appliances, including removable, fixed appliances, headgear, lip bumper and rapid maxillary expansion (Albino *et al.*, 1994).

Observational studies:

In the observational studies, similar data were collected. A number of different questionnaires were used and, interestingly, the most commonly used questionnaires in the observational studies were different to that used in the RCTs. The most commonly used questionnaires were the Rosenberg Self-Esteem Scale (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Jung, 2010; Arrow *et al.*, 2011), the Oral Health Impact Profile-14 (de Oliveira and Sheiham, 2003; 2004; Arrow *et al.*, 2011; Feu *et al.*, 2013) and the Child Perceptions Questionnaire 11-14 (CPQ 11-14) (Taylor *et al.*, 2009; Agou *et al.*, 2011; Benson *et al.*, 2015).

None of the observational studies reported the type of malocclusion which the participants presented with which limits conclusions which can be drawn. Six studies reported the type of treatment; three studies specified the use of fixed appliances (Agou *et al.*, 2011; Arrow *et al.*, 2011; Feu *et al.*, 2013) and three studies reported the use of removable and/or fixed appliances (Birkeland *et al.*, 2000; Schmidt *et al.*, 2008; Jung, 2010). The remaining studies did not specify the type of orthodontic treatment (Korabik, 1994; Mandall *et al.*, 1999; de Oliveira and Sheiham, 2003; 2004; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Taylor *et al.*, 2009; Badran, 2010; Benson *et al.*, 2015).

Although several studies were longitudinal studies, some of the psychosocial and OHRQoL measures were used only at the end of the treatment/observational period and not at baseline. Therefore, changes in these measures over time could not be determined (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Arrow *et al.*, 2011). This is a clear limitation when drawing conclusions.

Summary:

The majority of RCTs reported the malocclusions included however, none of the observational studies specified this. This is a concern as it limits conclusions which can be drawn and comparisons which can be made between studies. The type of treatment undertaken was reported in the majority of studies, but not all, and included fixed appliances, removable appliances and orthopaedic/functional appliances. Of note was the range of questionnaires used and the utilisation of different questionnaires in the RCTs and the observational studies; again this limits the comparisons which can be made between studies.

- **Ethical approval:**

Randomised Controlled Trials (RCTs):

One study reported obtaining ethical approval (Mandall *et al.*, 2010; 2012), while the remaining three did not report this.

Observational studies:

There were seven studies which reported obtaining ethical approval (de Oliveira and Sheiham, 2003; 2004; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Badran, 2010; Agou

et al., 2011; Arrow *et al.*, 2011; Feu *et al.*, 2013; Benson *et al.*, 2015), while the remaining studies did not report obtaining approval.

- **Funding:**

Randomised Controlled Trials (RCTs):

All four of the randomised controlled trials (RCTs) reported that they had funding.

Observational studies:

Six of the observational studies reported funding (de Oliveira and Sheiham, 2003; 2004; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Taylor *et al.*, 2009; Arrow *et al.*, 2011; Feu *et al.*, 2013; Benson *et al.*, 2015), while the remaining seven studies did not report whether or not they were funded (Korabik, 1994; Birkeland *et al.*, 2000; Mandall *et al.*, 1999; Schmidt *et al.*, 2008; Badran, 2010; Jung, 2010; Agou *et al.*, 2011).

Table 12: Study characteristics

Author (year)		Sample characteristics	Study design	Data collected and patient/ treatment characteristics	Drop-out/ Loss to follow-up		Ethical approval
					Number	Reasons	
Randomised Controlled Trials (RCTs)							
5 & 6	O'Brien <i>et al.</i> (2003, 2009)	<p>Country: UK</p> <p>Setting: NHS hospitals (n=14 clinicians)</p> <p>Age at recruitment: Early treatment Gp: <i>Start (2003 data):</i> 9.7 yrs (SD 0.98 yrs) <i>Start of Phase 2 of study (2009 data):</i> 12.41 yrs (SD=1.16 yrs)</p> <p>Control Gp (adolescent treatment): <i>Start (2003 data):</i> 9.8 yrs (SD 0.94 yrs) <i>Start of Phase 2 of study (2009 data):</i> 12.1 yrs (SD=1.0 yrs)</p> <p>Number of participants: Total: 176 Early Treatment Gp (n) <i>Start:</i> 89 (48 M; 41 F)</p>	<p>Multicentre RCT</p> <p>Prospective</p> <p>Length of follow up: 2003 paper = 15 mths 2009 paper = To end of orthodontic treatment</p> <p>Total length of study: 10 yrs approximately</p>	<p>Data collected: Study models</p> <p>Lateral cephalograms</p> <p>Questionnaires: - Piers Harris Children's Self-concept Scale (2003 and 2009 publications) - Childhood Experience Questionnaire (2003 publication only)</p> <p>Malocclusion type: Class II Division 1</p> <p>Type of orthodontic intervention: Clark Twin-Block functional appliances and fixed appliances</p>	44 (2003) 49 (2009)	<p>Questionnaires not completed (2003)</p> <p>Treatment not completed (2003)</p> <p>Incomplete data, Detection of bias due to inconsistent replies (2003)</p> <p>Dropped out of treatment (2009)</p> <p>Accepted occlusion (2009)</p>	N/R

		<p>15 mth follow-up (2003 data): 64 End of treatment follow-up (2009 data): 54</p> <p>Control Gp (adolescent treatment) (n) Start: 87 (46 M; 41 F) 15 mth follow-up (2003 data): 68 End of treatment follow-up (2009 data): 73</p> <p>Ethnicity: N/R</p> <p>Sample size calculation: Yes (Based on the PAR Index)</p> <p>Funding: Yes (Medical Research Council, UK)</p>					
7 & 8	Mandall et al. (2010, 2012)	<p>Country: UK</p> <p>Setting: 8 NHS hospitals - Orthodontic departments.</p> <p>Age at recruitment: Range: 7-9 yrs Treatment gp: Start: 8.7 yrs (SD. 0.9 yrs) 3 y Follow up: 12.1 yrs (SD 0.9 yrs)</p>	<p>Multicentre RCT</p> <p>Prospective</p> <p>Length of follow up: 15 mths follow-up 3 yrs follow-up</p>	<p>Data collected: Clinical examination</p> <p>Study models</p> <p>Lateral cephalograms</p> <p>TMJ examination</p> <p>Questionnaires: - Piers Harris Children's Self-</p>	<p>4 (2010)</p> <p>10 (2012)</p>	<p>Refused alginate impressions (2010)</p> <p>Failed to attend multiple appointments (2012)</p>	Yes

		<p>Control gp: Start: 9 yrs (SD. 0.8 yrs) 3 y Follow up: 12.3 yrs (SD 0.8 yrs)</p> <p>Number of participants: Total: Start: 73 15 month follow-up: 69 3 y Follow-up: 63 (30 M; 33 F)</p> <p>Treatment GP (n) Start: 35 (18 M; 17 F) 15 m follow-up: 33 3 y follow-up: 30 (15 M; 15 F)</p> <p>Control GP (n) Start: 38 (16 M; 22 F) 15 m follow-up: 36 3 y follow-up: 33 (15 M; 18 F)</p> <p>Ethnicity: Caucasian</p> <p>Sample size calculation: Yes (Based on the PAR Index)</p> <p>Funding: Yes British Orthodontic Society Foundation (BOSF) UK and TP Orthodontics</p>		<p>concept Scale (short-version) - Oral Aesthetic Subjective Impact Scale (OASIS)</p> <p>Malocclusion type: Class III</p> <p>Type of orthodontic intervention: Facemask appliance with Rapid Maxillary Expansion</p>			
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9	Albino <i>et al.</i> (1994)	<p>Country: USA</p> <p>Setting: University Clinic</p> <p>Age at recruitment: Range 11-14 yrs (Mean 12.5 yrs)</p> <p>Ethnicity: 83 Caucasian 10 Non-Caucasian</p> <p>Sample size calculation: N/R</p> <p>Number of participants: Total: Start: 93 (47 M; 46 F) Finish: 76</p> <p>Treatment Gp (n) Start: 44 Finish: 39</p> <p>Control Gp (n) Start: 49 Finish: 37</p> <p>Ethnicity: 83 Caucasian 10 Non-Caucasian</p> <p>Sample size calculation: N/R</p>	<p>Longitudinal randomised control type design (control group was a delayed treatment group)</p> <p>Prospective</p> <p>Length of follow up: 1 yr after completion of treatment</p>	<p>Data collected: Clinical examination</p> <p>Questionnaires: - Coopersmith Self-Esteem Scale - Rosenberg Self-Esteem Scale - Social Competence and Goals - Body Image Scale - Child Perception of Occlusion</p> <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: Removable, Fixed appliance, Headgear or Lip bumper or Rapid Maxillary Expansion</p>	17	<p>Treatment group: Moved from the area; personal considerations; repeated failure to keep appointments</p> <p>Control group: Sought treatment elsewhere due to delayed treatment related to their group assignment.</p>	N/R
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		Funding: Yes (NIH-NIDR - National Institute of Dental Research)					
11	Dann <i>et al.</i> (1995)	Country: USA Setting: University of North Carolina Orthodontic Clinic Patients recruited: Two groups of patients were recruited in this study (i) patients in an existing RCT allocated to treatment or control groups and (ii) graduate clinic patients. Only data for the RCT group was presented for the psycho-social measures Age at recruitment: RCT Gp: 9.3 yrs (SD 1.1 yrs) Graduate clinic Gp: 11.4 yrs (SD 1.6 yrs) Number of participants: Total: 208 T1: RCT Gp: 104 Graduate Clinic Gp: 104	Randomised Controlled Trial Longitudinal Prospective Length of follow up: 15 mths	Data collected: Study models Lateral cephalograms Questionnaires: - Piers Harris Children's Self-concept Scale Malocclusion type: Class II Type of orthodontic intervention: Functional appliance or headgear	17	n=2 excluded due to highly inconsistent questionnaire responses. Remainder did not reach T2 in the timescale of the study therefore data reported only for 87 participants	N/R

		or 105 (unclear - reported as both in the paper) T2: (after 15 mths of early growth modification) RCT Gp: 87 Ethnicity: Caucasian Sample size calculation: N/R Funding: Yes (National Institute of Dental Research and Orthodontic Fund; Dental Foundation of North Carolina)					
Author (year)	Sample characteristics	Study design	Data collected and patient/ treatment characteristics	Drop-out/ Loss to follow-up		Ethical approval	
				Number	Reasons		
Observational studies							
1 & 2	de Oliveira and Sheiham (2003, 2004)	Country: Brazil Setting: Schools Age at recruitment: 15-16 yrs Number of participants:	Observational Cross-sectional Prospective Length of follow up: N/A (Cross-sectional study)	Data collected: Clinical examination Questionnaires: - Oral Impacts on Daily Performance (OIDP) - Oral Health Impact Profile (OHIP-14) Malocclusion type: N/R	N/A	Cross-sectional study. At one time point Percentage completion: Reported in the de Oliveira and Sheiham (2004)	Yes

		Total: 1675 (724 M; 951 F) Treated Gp (Gp 1): 258 Currently under Rx. (Gp 2): 1060 Untreated (Gp 3): 357 Ethnicity: N/R Sample size calculation: Yes (Based on the prevalence of oral health impact on daily performances) Funding: Yes		Type of orthodontic intervention: N/R		publication as 100% although not quoted in the 2003 paper	
3 & 4	Kenealy <i>et al.</i> (2007) Shaw <i>et al.</i> (2007)	Country: UK Setting: At T1: Mobile dental unit At T2, T3 and T4: Cardiff Dental School, University Hospital of Wales Age at recruitment: At T1: 11-12 yrs At T2: 14-15 yrs At T3: 19-20 yrs At T4: range: 29.67- 32.42 yrs and mean 31.25 yrs (SD. 0.62 yrs) Number of participants:	Observational Longitudinal Prospective Length of follow up: 20 yrs	Data collected: Clinical examination Study models Multiple Questionnaires administered in 2000-2001 including (NB: not all included at earlier time point) including: - Rosenberg Self-Esteem Scale - Social Comparison Tendency - Satisfaction with Life Scale (SWLS) - WHO WHOQOL-BREF QoL Scale - Short Form 36 (SF36) - General Health Questionnaire (GHQ) - Centre for Epidemiological Studies Depression Scale (CES-D)	Kenealy <i>et al.</i> (2007): 681 Shaw <i>et al.</i> (2007): 686 (Calculated)	Kenealy <i>et al.</i> (2007): Contact details only available for n=733. n=4 not analysed due to incomplete data. Remainder: no response to recall; moved away/abroad; died; declined to continue in the study; agreed to continue in	Yes

		<p>At T1: 1,018 At T2: 792 At T3: 456 At T4: 337, but complete psychosocial data available for 332 only (144 M; 188 F)</p> <p>Ethnicity: Caucasian</p> <p>Sample size calculation: N/R</p> <p>Funding: Yes (Welsh Office, Department of Health; MRC and NHS R&D Programme)</p>		<ul style="list-style-type: none"> - Perceived Stress Scale (PSS) - Iowa-Netherlands Comparison - Orientation Measure (INCOM) - Social Interaction Anxiety Scale (SIAS) - Social Phobia Scale (SPS) - Generalized Self-Efficacy Scale (GSES) - Life Events Inventory (LEI) - Health Value Scale (HVS) - Dental Health Beliefs (HBM) <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: N/R</p>		<p>study but did not attend.</p> <p>Shaw <i>et al.</i> (2007): Contact details for 20-year follow-up only available for n=733; no response; failed to return completed data; declined to take part in psychological component of the study</p>	
10	Korabik (1994)	<p>Country: Canada</p> <p>Setting: University Orthodontic clinic</p> <p>Age at recruitment: Range: 11.4 to 16.4 yrs Mean: 13.3 yrs</p> <p>Number of participants: Total: 81 (27 M; 54 F) Treatment Gp 1: 30 (8 M; 22 F) Treatment Gp 2: 22 (11 M; 11 F)</p>	<p>Observational</p> <p>Quasi-experimental (cross-sectional/longitudinal)</p> <p>Prospective</p> <p>Length of follow up: 9.6 mths (SD=6.8 mths)</p>	<p>Data collected:</p> <p>Questionnaires: - Piers Harris Self-concept Scale</p> <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: N/R</p>	23	Discharge or transfer from the program, failure to collect complete data	N/R

		Treatment GP 3: 12 (4 M; 8 F) Treatment GP 4: 17 (4 M; 13 F) Ethnicity: N/R Sample size calculation: N/R Funding: N/R					
12	Birkeland et al. (2000)	Country: Norway Setting: Schools Age at recruitment: Start: 11yrs Follow-up: 15 yrs Number of participants: Start: 359 Follow-up: - 293 (138 M; 155 F) completed the questionnaires - 224 (104 M; 120 F) had clinical examinations and completed the questionnaires Ethnicity: N/R	Observational Longitudinal Prospective Length of follow up: 4 yrs	Data collected: Clinical examination Study models Questionnaire: Global Negative Self-Evaluation Scale Malocclusion type: N/R Type of orthodontic intervention: Removable and fixed appliances	66 (Figure calculated by the researcher from the paper) The paper quotes a 17% dropout over 4 year period (However, the researcher's calculated value was 18%)	Unknown reasons; Moved; Declined to re-attend.	N/R

		Sample size calculation: N/R Funding: N/R					
13	Mandall <i>et al.</i> (1999)	Country: UK Setting: Community/ Schools in Manchester Age at recruitment: 14-15 y Number of participants: 434 (334-response 77%) Ethnicity: Asian and Caucasian Sample size calculation: Yes (Based on the participants' perception of their own dental appearance) Funding: N/R	Observational Cross-sectional Prospective Length of follow up: N/A (Cross-sectional study)	Data collected: Clinical examination Questionnaires: - The Oral Aesthetic Subjective Impact Scale (OASIS) Malocclusion type: N/R Type of orthodontic intervention: N/R	100 failed to respond	Cross sectional study n=100 failed to respond (77% response)	N/R

14	Schmidt <i>et al.</i> (2008)	<p>Country: Germany</p> <p>Setting: South Germany; Community Practice</p> <p>Age at recruitment: Pre-Rx Gp. (Gp 1) = 4 to 13/14 yrs Mean age: 10 yrs</p> <p>Post-Rx Gp. (Gp 2)= 10-18 yrs Mean age: 14 yrs</p> <p>Number of participants: Total: 235 (7 additional patients refused to participate) Pre-Rx Gp (Gp 1): 116 (44 M; 72 F) Post-Rx Gp. (Gp 2): 119 (58 M; 61 F)</p> <p>(NB: Gp 1 and Gp 2 were different patients cohorts)</p> <p>Ethnicity: N/R</p> <p>Sample size calculation: N/R</p> <p>Funding: N/R</p>	<p>Observational</p> <p>Cross-sectional</p> <p>Prospective</p> <p>Length of follow up: N/A (Cross-sectional study)</p>	<p>Data collected: Clinical examination</p> <p>Questionnaire: - KINDL questionnaire</p> <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: Removable or fixed appliances.</p>	N/R (7 patients refused to participate)	Cross-sectional study at one time point and all who agreed to participate completed the questionnaires	N/R
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15	Taylor <i>et al.</i> (2009)	<p>Country: USA</p> <p>Setting: University Clinic and Community Health Clinic in Seattle</p> <p>Age at recruitment: Range: 11-14 yrs Mean: 13 yrs</p> <p>Number of participants: Total: 293 Precomprehensive ortho (Gp 1): 93 Postinterceptive ortho (Gp 2): 44 Control (Gp 3): 156</p> <p>Ethnicity: White, Hispanic, Black, Asian and other</p> <p>Sample size calculation: N/R</p> <p>Funding: Yes</p>	<p>Observational</p> <p>Cross-sectional design with a longitudinal component (3 different groups assessed at different stages of treatment)</p> <p>Prospective</p> <p>Length of follow up: N/A (Cross-sectional study)</p>	<p>Data collected: Clinical examination</p> <p>Study models</p> <p>Questionnaires: - Child Oral Health Related Quality of Life (COHQoL) - Youth Quality of Life</p> <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: N/R</p>	N/R	<p>Cross-sectional study</p> <p>No percentage response reported</p>	N/R
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16	Jung (2010)	Country: Korea Setting: Schools Age at recruitment: Range 12-15 yrs Number of participants: Total: 4509 (2944 F; 1565 M) Ethnicity: N/R Sample size calculation: N/R Funding: N/R	Observational Cross-sectional Prospective Length of follow up: N/A (Cross-sectional study)	Data collected: Clinical examination Questionnaire: - Rosenberg Self-Esteem Scale Malocclusion type: N/R Type of orthodontic intervention: Removable or fixed appliances	N/R	Cross-sectional study, at one time point No percentage response reported – the author described recruiting 4,509 patients and data is supplied for all participants according to the tables	N/R
17	Agou <i>et al.</i> (2011)	Country: Canada Setting: Orthodontic clinics at University of Toronto Age at recruitment: Range: 11-14 yrs Mean: 12.9 yrs (SD 0.98 yrs) Number of participants: Total: 199 patients recruited. Follow-up data	Observational Longitudinal Prospective Length of follow up: 1 st retainer review.	Data collected: Clinical examination Study models Questionnaires: - Child Perception Questionnaire (CPQ 11-14) - Psychological well-being subscale of the Child Health Questionnaire Malocclusion type: N/R Type of orthodontic intervention:	81	Some waiting-list patients sought alternative care or relocated outside the city	Yes

		<p>reported for 118 participants (59 F; 59 M)</p> <p>Follow up: Treatment Gp (n) Start: 74</p> <p>Control Gp (n) Start: 44</p> <p>Ethnicity: 76% were Caucasian but the ethnicity of the remainder was not reported</p> <p>Sample size calculation: N/R</p> <p>Funding: N/R</p>		Fixed appliances			
18	Arrow <i>et al.</i> (2011)	<p>Country: Australia</p> <p>Setting: School Dental Service, South Australia</p> <p>Age at recruitment: T1: mean 13 yrs T2: after 2 yrs, participants were monitored for receipt of orthodontic treatment T3: mean 30 yrs (17 years later)</p> <p>Number of participants:</p>	<p>Observational</p> <p>Longitudinal</p> <p>Prospective</p> <p>Length of follow up: 17 yrs</p>	<p>Data collected: Clinical examination</p> <p>Questionnaires: - Rosenberg Self-Esteem Scale - Satisfaction with Life Scale (SWLS) - Oral Health Impact Profile (OHIP-14)</p> <p>Malocclusion type: N/R</p> <p>Type of orthodontic intervention: Fixed appliances</p>	<p>3477 for OHIP-14</p> <p>3478 for Satisfaction with Life Scale</p> <p>3483 for Rosenberg Self Esteem Scale</p>	<p>Unable to contact as not living in survey area; excluded due to invalid ID number; incomplete data</p>	Yes

		T1: 3925 T2: 3262 T3: 632 completed an initial questionnaire but QoL and psychosocial data reported for n=448 OHIP; n=447 Satisfaction with Life; n=442 for Self Esteem (The authors appear to have reported data only for those who also attended the clinical examination) Ethnicity: N/R Sample size calculation: N/R Funding: Yes					
19	Badran (2010)	Country: Jordan Setting: schools Age at recruitment: <i>Range: 14-16 yrs</i> <i>Mean: 15 yrs</i> Number of participants: Total: 410 (F 215; M 195) Ethnicity: N/R Sample size calculation:	Observational Cross-sectional Prospective Length of follow up: N/A	Data collected: Clinical examination: Study models Questionnaire: Global Negative Self-Evaluation Scale Malocclusion type: N/R Type of orthodontic intervention: N/R	N/A	Cross-sectional study. At one time point	Yes

		Yes					
		Funding: N/R					
20	Feu et al. (2013)	Country: Brazil Setting: university Hospital/ Public school Age at recruitment: <i>Range: 12- 15 yrs</i> <i>Mean: 13.7 yrs (SD 1.1 yrs)</i> Number of participants: Total: 318 Treatment group: 92 Control group: - Waiting list group: 124 - School group: 102 Ethnicity: N/R Sample size calculation: Yes Funding: Yes	Observational Longitudinal Prospective Length of follow up: 2 years	Data collected: Clinical examination Questionnaires: Oral Health Impact Profile (OHIP-14) Malocclusion type: N/R Type of orthodontic intervention: Fixed appliances	34 Treatment group: 5 Waiting list group: 23 School group: 6	Change address; withdraw from the study 17 waiting list patients excluded because they started treatment	Yes

21	Benson <i>et al.</i> (2015)	Country: UK Setting: schools Age at recruitment: T1: 11-12 yrs T2: 14-15 yrs Number of participants: (Baseline) T1: 374 (F 252; M 122) (Follow-up) T2: 217 (F 156; M 61) Ethnicity: N/R Sample size calculation: Yes Funding: Yes (British Orthodontic Society Foundation)	Observational Longitudinal Prospective Length of follow up: 3 years	Data collected: Clinical examination Questionnaires: CPQ 11-14 CHQ Child Self-Report Form (CHQ-CF87) Malocclusion type: N/R Type of orthodontic intervention: N/R	157 (for those with and without baseline self-esteem data) 210 (for those with self-esteem data)	Withdrew consent Absent from school or not available at T2 Completed questionnaires but refused clinical examination	Yes
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2.3.2.2 Outcomes (Tables 13-27):

- **Piers-Harris Self-Concept Scale (four studies) (Tables 13 and 14):**
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Randomised Controlled Trials (RCTs):

Two RCTs used the Piers Harris scale to evaluate the effect of early orthodontic treatment for Class II malocclusion on self-concept (Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009) and one used it for Class III malocclusion (Mandall *et al.*, 2010; 2012).

A multi-centre randomised controlled trial conducted by O'Brien *et al.* (2003) investigated psychosocial benefits of early orthodontic treatment in Class II Division 1 patients using a Clark Twin-block appliance. The results showed very similar mean total scores for the two groups at T1 (58.37 and 58.17 for the early treatment and control groups, respectively). At T2 (following the functional treatment phase) the mean total score for the early treatment group was higher than that for the control group (63.32 and 59.69, respectively). There was a significant difference, when controlling for scores at baseline by regression analysis ($p=0.013$). However, when the study was continued to T3, there was no statistically significant difference between the early treatment and the adolescent treatment groups (O'Brien *et al.*, 2009), with scores for both groups increasing at that stage (68.87 and 68.04 for the treatment and control/later treatment group, respectively). It is of note that the scores for both groups increased at T3 after both had undergone treatment and it is therefore not possible to comment on whether any changes were due to treatment or not. Ideally, further studies are needed to investigate these findings, but with a control/untreated group through to the end of the study. However, this is clearly impossible due to ethical issues.

Dann *et al.* (1995) also assessed self-concept of children with Class II malocclusions following phase 1 treatment (headgear or functional appliance). The results showed a slightly greater mean change for the control group (4.5) than the treatment group (1.6) but there was no statistically significant difference between the two groups ($p=0.19$), and the authors also concluded that there was no relationship between self-concept score and the patient's age or extent of the overjet.

The effect of early orthodontic treatment for Class III patients under 10 years of age was studied by Mandall *et al.* (2010; 2012). The mean scores at baseline were

similar (51.0 and 48.9 for treatment and control groups, respectively) and the same applied at T2 (51.7 and 48.1 for the treatment and control groups). Multiple linear regression showed that there was no statistically significant difference in self-concept between the two groups at either time point ($p=0.22$); nor was there any significant difference at T3 ($p=0.56$) (Mandall *et al.*, 2012). Therefore, the authors concluded that there was no significant impact on self-concept in the short or longer term as a result of early orthodontic treatment with protraction headgear in Class III patients. It is of note that neither the treatment nor control group showed an obvious increase in self-concept between T1 and T3, unlike in the O'Brien *et al.* study (O'Brien *et al.*, 2003; 2009).

The different subscales of the Piers-Harris Self-Concept scale were also analysed in the studies (Table 14). In the O'Brien *et al.* (2003) study, there were statistically significant differences between the early treatment and control groups for four of the six subscales at T2: physical appearance, anxiety, popularity, and happiness/satisfaction, with p -values between 0.002 and 0.006. However, there were no statistically significant differences related to behaviour or intellectual/ school status (O'Brien *et al.*, 2003). There was no data regarding the subscales values at T3 (O'Brien *et al.*, 2009).

Mandall *et al.* (2010) and Dann *et al.* (1995), whilst using different statistical analyses, noted no statistically significant effects for the subscales.

Observational studies:

The study by Korabik (1994) categorised patients into four groups undergoing orthodontic treatment over a period of three years and self-concept was measured using the Piers-Harris Scale at different intervals before, during and after treatment. The results showed a statistically significant increase in total self-concept scores from start to end of treatment ($p<0.001$), but this improvement was only for patients who were tested within six months of removal of the appliances. When post-treatment measures were undertaken more than six months after completing treatment, there was no statistically significant improvement in self-concept. The authors concluded that orthodontic treatment does not appear to be associated with a long-lasting effect on self-concept. However, this study showed a high risk of bias due to the methodology involved and no sample size calculation was performed. Therefore, there are limitations to the conclusions which can be drawn. The

questionnaire scores are difficult to present due to the complex study design, but have been summarised in Table 13.

The different subscales of the Piers-Harris were analysed in the study and the paper reported no statistically significant effects, although no actual p-values were given (Table 14).

Summary:

The Piers-Harris Self-Concept Scale was the most commonly used questionnaire in the RCTs and was utilised in three of the four studies. One study reported psychosocial benefits from early orthodontic treatment of Class II division 1 malocclusions, with the treatment group having significantly better self-concept than the control/ delayed treatment group at the end of the functional appliance phase of treatment (O'Brien *et al.*, 2003); there did not appear to be a difference between the groups in the longer term although scores increased in both groups. The other studies found no statistically significant difference between the treatment and control groups. It is, however, important to consider whether sample size played a part in the lack of significant findings. There was no sample size calculation in the Albino *et al.* (1994) and Dann *et al.* (1995) studies which means there is a possibility that the studies were underpowered and this might affect the conclusions drawn.

Two studies did undertake sample size calculations for their studies, but this was based on the PAR Index and not on the Piers Harris Scale (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012). Therefore, retrospective sample size calculations based on the psychosocial outcome data were performed (Table 30). The O'Brien *et al.* (2003; 2009) study was potentially slightly underpowered at T2, with 75% power, but had adequate power at T3 (90%). While the Mandall *et al.* (2010; 2012) study was potentially slightly underpowered at both T2 (75%) and at T3 (70%). The sample size issues could have an impact on the findings, particularly for the Mandall study, although that was less likely for the O'Brien study.

Table 13: Study outcomes for studies using the Piers Harris Self-concept Scale (total score)

Randomised Controlled Trials (RCTs)								
Mean total score (SD unless specified otherwise)								
Author/year		T1 (Baseline)		T2 (15 months)		T3		Significance
		Early treatment (n=89)	Control/later treatment (n=87)	Early treatment (n=64)	Control/later treatment (n=68)	Early treatment	Control/later treatment	
5 & 6	O'Brien <i>et al.</i> (2003)	58.37 (95% CI 55.62 to 61.13)	58.17 (95% CI 55.46 to 60.88)	63.32 (95% CI 60.84 to 65.80)	59.69 (95% CI 56.70 to 62.67)	-	-	Data analysed using linear regression – the treatment group had significantly improved self-concept compared with the control group at T2 ($p=0.013$)
		T1 (Baseline)		T2		T3 (End of treatment)		Significance
		Early treatment (n=89)	Control/later treatment (n=87)	Early treatment	Control/later treatment	Early treatment (n=54)	Control/later treatment (n=73)	
	O'Brien <i>et al.</i> (2009)	60.33 (11.99)	61.78 (12.86)	-	-	68.87 (8.32)	68.04 (10.09)	No statistically significant difference between the early treatment and later treatment groups at T3

								taking other explanatory variables into account – however both groups showed increased scores
		T1 (Baseline)		T2 (15 months)		T3		Significance
		Treatment (n=35)	Control (n=38)	Treatment (n=33)	Control (n=36)	Treatment	Control	
7 & 8	Mandall <i>et al.</i> (2010)	51.0 (7.3)	48.9 (8.6)	51.7 (7.2)	48.1 (8.7)	-	-	No statistically significant difference between the two groups ($p=0.22$)
		T1 (Baseline)		T2		T3 (3 years)		Significance
		Treatment (n=35)	Control (n=38)	Treatment	Control	Treatment (n=30)	Control (n=33)	
	Mandall <i>et al.</i> (2012)	50.3 (6.8)	49.9 (8.1)	-	-	51.3 (8.7)	50.3 (6.9)	No statistically significant increase in self-concept in the Treatment Group compared with the Control Group ($p= 0.56$)

		T1	T2 (NB: Change in score + SD)			Significance		
		RCT group (Data was not subdivided into treatment or control groups at T1)	Group 1 (RCT group - Headgear and functional treatment groups)	Group 2 (RCT group - Control)				
11	Dann <i>et al.</i> (1995)	61.4 (11.9)	1.6 (9.2)	4.5 (9.8)	No statistically significant difference when comparing the treatment and control groups at T2 ($p=0.19$)			

Observational studies							
			T1 (Approx. 1 yr before treatment)	T2 (Just before treatment)	T3 (1 yr into treatment)	T4 [†] (After removal of appliances)	Significance
10	Korabik (1994)	Gp 1 (n=21)	65.60 (8.19)	63.00 (9.29)	63.38 (12.92)	65.29 (11.19)	Self-concept scores increased significantly after removal of appliances (p<0.001), but only for those within 6 mths of appliance removal
		Gp 2A (n=15)	63.60 (9.56)	65.13 (6.45)	63.47 (9.82)	62.40 (11.16)	
		Gp 2B (n=12)	-	-	62.08 (8.62)	63.08 (10.54)	
		Gp 3 (n=10)	-	66.50 (9.36)	65.80 (8.08)	-	
		† 3 separate groups 0-6 mths post-debond; 7-10 mths or 11 mths and longer					

Table 14: Study outcomes for studies using the Piers Harris Self-concept Scale (Subscale scores)

Randomised Controlled Trials (RCTs)									
Subscales scores mean (SD or 95% CI)									
Author/year		Subscales	T1		T2		T3		Significance [†]
			(Baseline)		(15 month follow-up)				
			Early treatment	Control	Early treatment	Control	Early treatment	Control	
5	O'Brien <i>et al.</i> (2003)	Behaviour	13.68 (13.08 to 14.28)	13.28 (12.61 to 13.95)	14.20 (13.68 to 14.72)	14.03 (13.43 to 14.63)	-	-	<i>p</i> =0.87
		Intellectual and school status	12.66 (11.89 to 13.43)	12.66 (11.97 to 13.37)	13.53 (12.80 to 14.25)	13.06 (12.22 to 13.89)	-	-	<i>p</i> =0.30
		Physical appearance	7.83 (7.16 to 8.49)	8.34 (7.66 to 9.02)	9.23 (8.60 to 9.86)	8.24 (7.52 to 8.96)	-	-	<i>p</i> =0.002
		Anxiety	9.52 (8.77 to 10.27)	9.39 (8.57 to 10.20)	10.84 (10.14 to 11.54)	9.57 (8.70 to 10.44)	-	-	<i>p</i> =0.006
		Popularity	8.50 (7.90 to 9.12)	8.42 (7.78 to 9.05)	9.97 (9.48 to 10.46)	8.76 (8.05 to 9.74)	-	-	<i>p</i> =0.004
		Happiness and satisfaction	8.14 (7.61 to 8.66)	8.35 (7.83 to 8.88)	8.94 (8.60 to 9.27)	8.05 (7.57 to 8.54)	-	-	<i>p</i> <0.005
† All values are given with 95% CI and p-values obtained via regression analysis, controlling for baseline scores. The treatment group showed significantly better self-concept scores than the control group for the total score and for the Physical Appearance, Anxiety, Popularity and Happiness and Satisfaction subscales. When the size of the effect is considered, it appears that the treatment group results increase from 0.99 to									

		1.4 for Happiness and Satisfaction and Anxiety.								
		Subscales		T1 (Baseline)		T2 (15 month follow-up)		T3 (3 years follow-up)		Significance 2010 ♦ 2012 ♦
				Treatment	Control	Treatment	Control	Treatment	Control	
7 & 8	Mandall <i>et al.</i> (2010, 2012) (All values given with SD)	Behaviour	2010	13.1 (1.2)	11.7 (2.8)	13.0 (1.6)	12.5 (2.2)	-	-	<i>p</i> =0.30
			2012	13.0 (1.3)	11.8 (2.9)	-	-	12.8 (2.7)	12.7 (2.3)	<i>p</i> =0.73
		Intellectual and school status	2010	14.0 (2.2)	12.9 (3.3)	13.5 (2.7)	12.4 (3.3)	-	-	<i>p</i> =0.68
			2012	13.7 (2.3)	12.7 (3.2)	-	-	13.2 (3.3)	12.5 (3.1)	<i>p</i> =0.95
		Physical appearance	2010	8.5 (2.2)	8.5 (1.6)	8.4 (2.2)	7.5 (2.3)	-	-	<i>p</i> =0.10
			2012	8.3 (2.2)	8.7 (1.7)	-	-	8.8 (2.6)	8.9 (1.9)	<i>p</i> =0.77
		Anxiety	2010	11.5 (1.70)	11.1 (3.3)	11.5 (2.1)	11.2 (3.0)	-	-	<i>p</i> =0.92
			2012	11.4 (1.7)	11.2 (3.3)	-	-	11.7 (2.6)	11.5 (2.4)	<i>p</i> =0.97
		Popularity	2010	9.6 (2.5)	9.8 (2.7)	10.0 (2.1)	9.9 (2.4)	-	-	<i>p</i> =0.52
			2012	9.5 (2.5)	9.8 (2.8)	-	-	10.4 (2.3)	10.5 (1.6)	<i>p</i> =0.69
		Happiness	2010	8.9 (1.2)	4.4 (1.5)	8.7 (1.1)	8.6 (1.1)	-	-	<i>p</i> =0.77

		and satisfaction	2012	8.8 (1.2)	8.8 (1.50)	-	-	8.7 (1.3)	9.1 (1.1)	$p=0.23$
◇ Small increases and decreases were shown in both groups but no statistically significant differences ($p>0.05$).										
◆ When the treatment and control groups were compared from T1 to T3, there were small changes over time but no statistically significant changes in association with treatment.										
		Subscales	T1			T2 (After 15 months) (NB: Change in score + SD)			Significance [†]	
			RCT group (Data was not subdivided into treatment and control groups at T1)			Group 1 (RCT group - Headgear and functional treatment groups)		Group 2 (RCT group - Control)		
11	Dann <i>et al.</i> (1995)	Behaviour	14.0 (2.4)			-0.1 (2.4)		0.6 (2.4)	$p=0.22$	
		Intellectual and school status	13.7 (3.2)			0.2 (2.3)		1.0 (2.5)	$p=0.16$	
		Physical appearance	8.9 (3.0)			0.2 (2.8)		1.5 (3.0)	$p=0.05$	
		Anxiety	10.6 (3.1)			0.7 (2.6)		0.5 (2.2)	$p=0.71$	
		Popularity	7.7 (3.0)			0.4 (2.6)		1.5 ^{††} (2.6)	$p=0.03$	
		Happiness and satisfaction	8.5 (2.1)			0.4 (2.0)		0.2 (1.8)	$p=0.97$	
		† At T2 the magnitude of the mean changes was small for both groups, with only one domain in Group 2 showing a statistically significant change. Given the conservative levels chosen for testing the significance of the multiple comparisons being made ($p<0.01$), there was no difference in the mean changes between the two groups.								
Observational studies										
		Subscales		T1 (Year 1)	T2 (Year 2)	T3 (Year 3)	T4 (Year 4)		Significance	
10	Korabik (1994)	Behaviour	Gp1	14.00 (1.93)	14.48 (2.14)	14.62 (2.33)	13.95 (2.94)		Various group x time interactions were undertaken but no statistically significant	
			Gp 2A	-	14.33 (1.72)	13.73 (2.37)	12.00 (3.84)			

			Gp 2B	14.90 (0.99)	-	13.92 (1.98)	14.08 (2.02)	changes noted.
			Gp 3	-	14.10 (2.69)	13.90 (2.69)	-	
		Intellectual and school status	Gp1	14.60 (2.10)	14.19 (2.50)	14.38 (2.71)	14.05 (3.23)	No actual p-values give (only $p>0.05$)
			Gp 2A	-	14.33 (2.35)	14.07 (2.58)	13.13 (3.34)	
			Gp 2B	14.90 (2.08)	-	13.58 (2.84)	12.58 (3.90)	
			Gp 3	-	15.40 (1.71)	14.80 (2.04)	-	
		Physical appearance	Gp1	10.13 (3.00)	9.19 (2.77)	9.00 (2.98)	9.95 (3.47)	
			Gp 2A	-	9.53 (2.39)	9.67 (2.55)	10.27 (2.82)	
			Gp 2B	8.10 (3.04)	-	8.33 (3.20)	9.42 (3.37)	
			Gp 3	-	9.20 (2.62)	9.69 (1.96)	-	
		Anxiety	Gp1	11.60 (2.10)	10.05 (2.92)	10.55 (2.28)	10.81 (2.52)	
			Gp 2A	-	11.60 (2.06)	11.07 (2.25)	10.80 (3.01)	
			Gp 2B	10.30 (2.75)	-	10.67 (2.93)	10.42 (2.84)	
			Gp 3	-	12.60 (1.78)	12.20 (2.20)	-	
		Popularity	Gp1	9.60 (2.64)	9.00 (2.49)	9.45 (2.04)	9.48 (2.29)	
			Gp 2A	-	9.73 (2.05)	9.53 (2.59)	9.93 (2.05)	
			Gp 2B	9.30 (1.64)	-	9.92 (2.15)	9.58 (2.35)	

			Gp 3	-	10.00 (2.21)	10.69 (0.97)	-	
		Happiness and satisfaction	Gp1	9.07 (1.16)	8.71 (1.68)	8.81 (1.91)	9.14 (1.32)	
			Gp 2A	-	8.93 (1.28)	8.53 (1.46)	8.87 (1.55)	
			Gp 2B	8.70 (1.42)	-	7.92 (2.27)	8.08 (1.68)	
			Gp 3	-	9.40 (1.58)	9.50 (0.53)	-	

- **Rosenberg Self-Esteem Scale (Table 15):**

Randomised Controlled Trials (RCTs):

There were no RCTs which reported the use of the Rosenberg Self-Esteem Scale.

Observational studies:

Three observational studies used the Rosenberg Self-Esteem Scale but there were no statistically significant improvements in self-esteem reported in conjunction with orthodontic treatment (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Jung, 2010; Arrow *et al.*, 2011).

Kenealy *et al.* (2007) and Shaw *et al.* (2007) conducted a 20-year longitudinal follow-up study and analysis at the final time point suggested that the participants who had orthodontic treatment had statistically significant better self-esteem than the non-treated group (mean values 32.93 and 31.50 for treated and non-treated groups; $p=0.005$). However, when the data was analysed with self-esteem at T1 as a covariate, there was no longer a statistically significant difference.

Similarly, a 17-year observational study conducted by Arrow *et al.* (2011) evaluated the quality of life and psychosocial outcomes among a cohort of adults who were initially examined as adolescents, but found no statistically significant difference between those patient who underwent treatment and a community sample (mean values 22.94 and 22.54; $p=0.44$). The authors concluded that fixed orthodontic treatment did not appear to be associated with improved self-esteem, however, it must be noted that this was based on post-treatment scores only and no baseline scores were reported. The limitations due to the high percentage dropout in this study should also be borne in mind.

A cross-sectional study by Jung (2010) showed that, for girls, crowding of the anterior teeth, lip protrusion and lack of orthodontic intervention were associated with statistically significantly lower self-esteem scores, while there were no statistically significant differences for boys. For girls, self-esteem increased significantly after fixed appliance treatment while for boys there was no statistically significant difference following treatment (NB: the scores were divided by 10 for analysis in this paper hence the difference in scores reported in Table 15). The

authors concluded that gender may play a role in the relationship between malocclusion, self-esteem and fixed appliance treatment, and that treatment of malocclusion may affect self-esteem more in adolescent girls than boys.

Summary:

Three observational studies used the Rosenberg Self-Esteem Scale. Two longitudinal studies suggested that there was no statistically significant difference in self-esteem after orthodontic treatment (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Arrow *et al.*, 2011), although one cross-sectional study found that there was a gender effect for self-esteem and the paper concluded that not having undergone orthodontic treatment resulted in statistically significantly lower self-esteem scores in girls but not in boys (Jung, 2010).

The limitations of these studies should however be borne in mind, with high percentage loss to follow-up in both of the longitudinal studies (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Arrow *et al.*, 2011).

Table 15: Study outcomes for studies using the Rosenberg Self-Esteem Scale

Observational studies								
Total score: Mean (SD)								
Author (year)		T1 (Start - 1981)		T2 (1984)		T3 (2000 - 2001) (20 yrs follow - up)		Significance
		Treated	No treatment	Treated	No treatment	Treated	No treatment	
3	Kenealy <i>et al.</i> (2007)	-	-	-	-	32.93 (4.34)	31.50 (4.82)	Treated group had significantly higher self-esteem than non-treated group ($p=0.005$) at T3 However when baseline self-esteem was accounted for, this difference was no longer statistically significant

		No orthodontic treatment (n=181)		Received orthodontic treatment (n=150)		Significance		
		Gp.1 (Rx need in 1981 n=124)	Gp.2 (No Rx need in 1981 n=57)	Gp. 3 (Rx need in 1981 n=138)	Gp. 4 (No Rx need in 1981 n=12)			
4	Shaw <i>et al.</i> (2007)	31.40 (4.83)	31.63 (4.84)	32.99 (4.25)	32.25 (5.41)	$p=0.014$ (between Gp.1 and 3). The association between orthodontic treatment and self-esteem in adulthood was accounted for by self-esteem at baseline. When data was re-analysed with self-esteem in 1981 as a covariate, the variables were no longer significant.		
		T1 (Start - 1988/1989)		T2 (After 2 years - 1990/1991) (Monitored for receipt of fixed orthodontic treatment)		T3 (After orthodontic treatment - 2005/2006)		Significance
		Treatment group	Community group	Treatment group	Community group	Treatment group (n=442)	Community group (n=111)	
18	Arrow <i>et al.</i> (2011)	-	-	-	-	22.94 (SE=0.23)	22.54 (SE=0.49)	$p=0.44$ No statistically significant difference between treatment and community groups at T3

		Groups	Cross sectional study design		Significance
			Boys (n=1565)	Girls (n=2944)	
16	Jung (2010)	Finished fixed appliance treatment	2.89 (0.48)	2.86 (0.43)	No actual p-values quoted The authors state that: - For females self-esteem increased significantly after fixed appliance treatment - For males there was no statistically significant difference following orthodontic treatment
		During fixed appliance treatment	2.86 (0.46)	2.75 (0.42)	
		During or finished removable appliance treatment	2.76 (0.41)	2.75 (0.47)	
		No orthodontic treatment	2.80 (0.47)	2.71 (0.45)	
		NB: Scores were divided by 10 for analysis, therefore, scores must be multiplied by 10 for comparisons.			

- **Global Negative Self-Evaluation Scale (Two studies) (Table 16):**

Randomised Controlled Trials (RCTs):

There were no RCTs which reported use of the Global Negative Self-Evaluation Scale.

Observational studies:

Two observational studies used this scale. A cross-sectional study conducted by Badran (2010) found that those who had a history of orthodontic treatment reported significantly higher self-esteem than those with no history of treatment, but stated that the correlation was weak ($r=0.165$, $p<0.05$). However, there was no data presented in the paper so it was not possible to draw further conclusions. The author was contacted to request further information but no reply was received.

Birkeland *et al.* (2000) undertook a longitudinal study in which the Global Negative Self-Evaluation Scale were completed by participants at 11 years (T1) and 15 years of age (T2). At T2, some children had undergone treatment with removable or fixed appliances but others were untreated and acted as a “control” group. There were statistically significant improvements in self-esteem for those patients in the fixed appliance group and the control group, but not for the removable appliance group. This may, however, have been because the group size was very small ($n=15$). The results for the two treated groups together showed that they had statistically significantly higher self-esteem at T2 than the untreated group, but a similar tendency also existed at T1 ($p=0.08$). There was an overall improvement in self-esteem with age from T1 to T2 ($p<0.001$) and the authors suggested that the increase in self-esteem did not appear to be related to treatment and may be due to maturational changes. There was also a gender difference, which became more evident at T2, with more girls than boys showing negative self-evaluation.

Summary:

Two observational studies showed enhanced global self-evaluation scores following orthodontic treatment however, in one of the studies, the authors concluded that these changes appeared to be related to maturation rather than orthodontic treatment (Birkeland *et al.*, 2000). This conclusion was not clearly explained but was presumably due to changes in both the treatment and control groups. Again, the

limitations of the study must be considered, particularly the small size of some of the subgroups and the lack of a sample size calculation.

Table 16: Study outcomes for studies using the Global Negative Self Evaluation Scale

Observational studies											
Mean Score (SD)											
Author (year)		T1 (Pre-treatment)		T2 (Post-treatment)		T1-T2 Difference		Significance			
		Patient FA=49 RA=15		Patient FA=51 RA=16		Patient				Control	
		Removable appliance	Fixed appliance	Removable appliance	Fixed appliance	Removable appliance	Fixed appliance				
12	Birkeland <i>et al.</i> (2000)	1.7	2.4	2.5	1.8	2.0	2.2	-0.1 (0.8)	0.4 (1.1)	0.3 (1.1)	T1 - T2 difference: Removable Appliance (RA) <i>p</i> = 0.75 Fixed Appliance (FA) <i>p</i> = 0.009 Control/untreated <i>p</i> = 0.002 - Statistically significant improvement for FA and Control groups, but not for RA group (NB: group size was small for RA n=15). - For all patients combined, ANOVA showed statistically significant improvement from T1 to T2. - The two treated groups together had higher self-esteem at T2 than the untreated group, but this tendency also existed at T1 (<i>p</i> <0.05)

19	Badran (2010)				<p>The only evidence available is a statement saying: “<i>students who had received orthodontic treatment had significantly higher self-esteem than those who had not received treatment</i>” but the correlation was weak ($r=0.165$, $p<0.05$)</p>
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- **Coopersmith Self-Esteem Scale (one study) (Table 17):**
-

Randomised Controlled Trials (RCTs):

Albino *et al.* (1994) allocated participants to either a treatment or control/ delayed treatment group and the patients completed a number of psychosocial questionnaires at several time points, although data was reported for only three of these time points. Scores were similar for the treatment and control groups both before and after treatment (T1: 6.25 and 6.56 respectively T3: 7.22 and 7.25 respectively). Data were analysed by repeated measures multivariate analysis of variance, which assessed group differences at different time points, and the authors concluded that there was a statistically significant effect due to time ($p < 0.01$) but that the self-esteem changes appeared to be related to time rather than treatment.

The limitations of the study need to be borne in mind including the lack of a sample size calculation, the types of malocclusions included were not reported and different types of orthodontic treatment were included (removable and fixed appliances, headgear, lip bumper and rapid maxillary expansion). The different types of appliances used suggest that different types and severities of malocclusion were included and there may have been mild/ moderate malocclusions included which did not affect self-esteem to the same extent as more severe problems. Furthermore, there appeared to be systematic loss to follow-up, with more patients lost from the control group and it was not reported if the authors accounted for this loss in the analyses. These factors could introduce bias and affect the conclusions drawn.

Observational studies:

No observational study reported the use of the scale.

Table 17: Study outcomes for studies using the Coopersmith Self-Esteem Scale

Randomised Controlled Trials (RCTs)								
Total score means (SD)								
Author (year)		T1 (Before orthodontic treatment)		T2 (On completion of orthodontic treatment)		T3 (1 year after completion of orthodontic treatment)		Significance
		Treatment	Control	Treatment	Control	Treatment	Control	
9	Albino <i>et al.</i> (1994)	6.25 (1.81)	6.56 (2.26)	7.42 (1.90)	7.03 (2.09)	7.22 (2.29)	7.25 (2.38)	<p>Authors discussed self-esteem findings but did not state clearly if this was for the Coopersmith Self Esteem Scale or the Rosenberg Self Esteem Scale. It appeared to be for the former however.</p> <p>The authors stated that participants' self-concept scores increased with time and concluded that these changes were not attributable to treatment effects, but to the effect of time</p>
		NB: Data collected at 5 time points but only 3 time points reported.						

- **Satisfaction With Life Scale (Table 18):**

Randomised Controlled Trials (RCTs):

No RCTs reported the use of the Satisfaction With Life Scale.

Observational studies:

Two studies reported the use of this scale (Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Arrow *et al.*, 2011). In the Kenealy *et al.* (2007) paper, the mean scores at T3 were higher for the treated group than for the non-treated group (25.17 and 23.34 respectively) and this difference was statistically significantly ($p=0.016$). Shaw *et al.* (2007) concluded that participants with a prior need for treatment who received treatment showed a significantly greater satisfaction with life than those who did not receive treatment (Shaw *et al.*, 2007). It must, however, be noted that there were no baseline scores for the questionnaire, which limits the conclusions which can be drawn and the high percentage dropout must also be considered.

Arrow *et al.* (2011) evaluated quality of life and psychosocial outcomes among a cohort of adults who were initially examined as adolescents, but found no statistically significant difference between the treated and untreated/community group for this scale (mean scores 18.36 and 18.53, respectively). Again, it must be noted that there were no baseline scores for comparison and there was a high loss to follow-up in the study.

Table 18: Study outcomes for studies using the Satisfaction With Life Scale

Observational studies								
Mean Total score (SD)								
Author (year)		T1 (Start-1981)		T2 (1984)		T3 (2000-2001) (20 yrs follow-up)		Significance
		No treatment	Treated	No treatment	Treated	No treatment	Treated	
3	Kenealy <i>et al.</i> (2007)	-	-	-	-	23.34 (7.36)	25.17 (6.13)	<i>p</i> =0.016. The treated group had significantly higher scores than non treated group at T3
		T3 (2000-2001) (20 yrs follow-up)						Significance
		No orthodontic treatment (n=181)			Received orthodontic treatment (n=150)			
		Gp.1 (Rx need in 1981 n=124)	Gp.2 (No Rx need in 1981 n=57)		Gp. 3 (Rx need in 1981 n=138)	Gp. 4 (No Rx need in 1981 n=12)		
4	Shaw <i>et al.</i> (2007)	22.85 (7.55)	24.30 (6.89)		25.07 (6.12)	26.33 (6.51)		<i>p</i> =0.032. There was a statistical significant difference between Groups 1 and 3

Mean Total score (SE)								
		T1 (Start - 1988/1989)		T2 (After 2 years - 1990/1991) (Monitored for receipt of fixed orthodontic treatment)		T3 (After orthodontic treatment - 2005/2006)		Significance
		Treatment group	Community group	Treatment group	Community group	Treatment group (n=447)	Community group (n=111)	
18	Arrow <i>et al.</i> (2011)	-	-	-	-	18.36 (0.19)	18.53 (0.39)	$p= 0.69$. No statistically significant difference between the treatment and community groups

- **Child Perception Questionnaire (CPQ 11–14) (Table 19)**

[In association with Youth Quality of Life (YQoL) in the Taylor *et al.* (2009) study (Table 20) and the Child Health Questionnaire (Psychological well-being subscale) in the Agou *et al.* (2011) study (Table 21)].

Randomised Controlled Trials (RCTs):

No RCTs reported the use of the Child Perception Questionnaire (CPQ 11–14).

Observational studies:

Three observational studies evaluated OHRQoL using the CPQ 11–14; one was cross-sectional (Taylor *et al.*, 2009) and two were longitudinal (Agou *et al.*, 2011; Benson *et al.*, 2015).

The cross-sectional study by Taylor *et al.* (2009) classified participants into three different groups: Group 1 (pre-comprehensive orthodontic treatment), Group 2 (post-interceptive orthodontic treatment) and Group 3 (a non-orthodontic comparison). There was no statistically significant difference between the three groups for the total scores (mean scores 18.08, 19.00 and 17.97) or any of the subscales, with the exception of the oral health item where Group 2 perceived their oral health more positively than Group 1 ($p < 0.001$).

For the YQoL questionnaire, the mean scores were similar (82.59, 82.33 and 82.18) and there were no statistically significant differences between the three groups. The authors concluded that there was no significant association between malocclusion, orthodontic treatment and general QoL or OHQoL.

Agou *et al.* (2011) assessed OHRQoL using the CPQ 11-14, while controlling for individual psychological characteristics using the psychological well-being (PWB) subscale of the Child Health Questionnaire. The authors hypothesised that children with better psychological well-being (PWB) would experience fewer negative OHRQoL impacts, regardless of whether or not they underwent orthodontic treatment. The authors reported that the PWB remained relatively constant for both groups over time although no p-value was quoted.

A statistically significant difference in total CPQ score was reported between the treatment and control groups at T2 although no p-value was quoted. The mean CPQ

11–14 scores at T1 were 21.63 for the treatment patients who returned T2 questionnaires and 24.07 for the control group. At T2, the scores reduced to 16.16 and 23.14 for the treatment and control groups. Statistically significant differences were also reported for the Social Well-being (SWB) and Emotional Well-being (EWB) subscales scores (Table 19). When the Psychological Well-Being (PWB) subscale score was included as a covariate, the effect of orthodontic treatment was no longer significant for total CPQ 11–14 score or the Social Well-Being subscale. However, Emotional Well-Being remained statistically significant between the treatment and control groups when PWB scores were factored in.

The authors concluded that children with higher PWB scores showed better OHRQoL, regardless of whether or not they had orthodontic treatment. However, children with low PWB, who did not receive orthodontic treatment, reported poorer OHRQoL in comparison with those who received fixed appliance orthodontic treatment. This suggests that children with low PWB may benefit more from orthodontic treatment than those with high PWB.

Another longitudinal study conducted by Benson *et al.* (2015) investigated OHRQoL in adolescents over a 3 year period. There was an overall significant reduction in CPQ11-14 between T1 and T2 ($p=0.003$), which suggests improved OHRQoL over time. When the effect of orthodontic treatment was considered, the mean improvement in scores for those with a history of treatment was 3.2 and 2.4 for those with no history of treatment. However, the difference between the two groups was not statistically significant ($p=0.584$). Therefore, the authors concluded that OHRQoL improved in adolescents over time, regardless of whether they had orthodontic treatment and they suggested that individual and environmental factors might affect OHRQoL, which should be considered in future studies. The authors did however draw attention to the relatively low number of participants who had undergone treatment in the 3 year observation period ($n=33$ out of 173 with the longitudinal data, 19.1%).

Summary:

Three observational studies utilised the CPQ 11-14 but with varying conclusions. One cross-sectional study concluded that malocclusion and its treatment did not appear to be associated with significant effects on QoL or OHRQoL, although participants did report better self-ratings of oral health (Taylor *et al.*, 2009). The

Agou *et al.* (2011) study showed a statistically significant difference in CPQ 11-14 score between the treatment and control groups, but this difference was not significant when the Psychological Well-Being subscale score was included as a covariate. This suggests differences between participants with low or high PWB regarding affects of orthodontic intervention. Another longitudinal study by Benson *et al.* (2015) reported that OHRQoL improved in adolescents over time whether they underwent orthodontic treatment or not and it was suggested that other individual and environmental factors may affect OHRQoL and should be explored in future studies.

Table 19: Study outcomes for studies using the Child Perception Questionnaire (CPQ 11-14)

Observational studies					
Mean score (SD)					
Author (year)		Group 1 Pre-comprehensive orthodontic group	Group 2 Post-interceptive orthodontic group	Group 3 Paediatric dental group (Non-orthodontic Comparison)	Significance \diamond
15	Taylor <i>et al.</i> (2009)	18.08 (11.83)	19.00 (12.73)	17.97 (11.07)	$p= 0.94$
	Subscale scores				
	Oral symptoms	25.67 (12.58)	30.02 (13.59)	27.86 (13.27)	$p= 0.13$
	Functional limitations	18.57 (12.05)	19.38 (12.97)	17.88 (12.88)	$p= 0.54$
	Emotional well-being	18.43 (17.47)	18.45 (20.57)	18.57 (16.88)	$p= 0.78$
	Social well-being	14.05 (14.08)	14.07 (14.31)	13.12 (12.17)	$p= 0.91$
	Oral health item	1.95 (0.82)	1.36 (0.84)	1.68 (0.90)	$p< 0.001 \blacklozenge$
	Oral impact item	1.30 (1.09)	1.53 (0.95)	1.34 (1.08)	$p= 0.21$
	<p>\diamond There was no difference between the three groups in total score or any of its domains with the exception of the item regarding oral health; Group 2 perceived their oral condition significantly more positively than Group 1 ($p<0.001$). Group 3 participants had an average score on this item which was between Groups 1 and 2 responses and did not differ significantly from either group.</p> <p>$\blacklozenge p<0.001$; statistical tests showed that the only significant difference was between the pre-comprehensive (Gp 1) and post-interceptive groups (Gp 2) ($p< 0.001$) for the oral health item.</p>				

Author (year)		T1				T2		Significance*
		All treatment group (n=98)	Treatment group who returned T2 data only (n=74)	All controls (n=101)	Controls who returned T2 data only (n=44)	Treatment group (n=74)	Control (n=44)	
17	Agou <i>et al.</i> (2011)	21.05 (15.09)	21.63 (14.19)	24.07 (16.15)	24.07 (16.15)	16.16 (10.99)	23.14 (17.97)	A statistically significant difference in total CPQ score was observed between patients and controls at T2 (No <i>p</i> -value quoted). However, when Psychological Well-Being (PWB) score was incl. as a covariate, the difference between treatment and control groups became non significant (No <i>p</i> -value quoted)
	Subscale scores							
	Oral symptoms (OS)	5.58 (13.40)	5.75 (3.37)	5.93 (3.24)	6.07 (3.59)	5.26 (3.15)	6.34 (3.69)	No statistically significant differences between groups at T2
	Functional limitations (FL)	5.09 (4.15)	5.27 (4.15)	5.92 (4.95)	5.36 (4.69)	5.41 (4.26)	4.82 (4.57)	No statistically significant differences between groups at T2
	Emotional well-being (EWB)	5.19 (5.09)	5.29 (5.14)	6.83 (5.59)	6.75 (5.45)	2.51 (2.96)	6.82 (7.56)	A statistically significant difference in EWB score was observed between patients

								and controls at T2 (No <i>p</i> -value quoted).
								When Psychological Well-Being (PWB) score was incl. as a covariate, the difference between treatment and control groups was still statistically significant (No <i>p</i> -value quoted)
	Social well-being (SWB)	5.18 (5.39)	5.32 (5.46)	6.01 (6.12)	5.89 (6.13)	2.99 (3.59*)	5.16 (6.34)	A statistically significant difference in SWB score was observed between patients and controls at T2 (No <i>p</i> -value quoted).
								However, when Psychological Well-Being (PWB) score was incl. as a covariate, the difference between treatment and control groups became non- significant (No <i>p</i> -value quoted)
* Paired t statistics significant at <i>p</i> <0.01								
Mean score (SD)								
Author (years)		T1 (n=374)			T2 (n=217)		Significance	
21	Benson <i>et al.</i> (2015)	13.7 (8.2)			11.2 (6.7)		There was an overall significant reduction in the total CPQ11-14 score between T1 and T2 (mean difference = 2.0,	

				<p>SD= 8.7, $p=0.003$) suggesting that OHRQoL improved over time, regardless of whether or not they underwent orthodontic treatment.</p> <p>The mean improvement in the total CPQ11-14 was 3.2 (SD= 6.9; $p=0.009$) in those with a history of orthodontic treatment and 2.4 (SD= 8.8; $p<0.001$) in those with no history of orthodontic treatment, but the difference between the two groups was not statistically significant ($p=0.584$).</p> <p>- Only 35 out of 217 participants gave a history of orthodontic treatment between T1 and T2 (16.2%).</p>
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Table 20: Study outcomes for studies using the Youth Quality of Life (YQoL)

Observational studies					
Mean scores (SD)					
Author (year)		Group 1 Pre-comprehensive orthodontic group	Group 2 Post-interceptive orthodontic group	Group 3 Paediatric dental group (Comparison)	Significance [†]
15	Taylor <i>et al.</i> (2009)	82.59 (12.80)	82.33 (12.71)	82.18 (12.26)	$p= 0.85$
	Subscale scores				
	Sense of self	79.13 (14.83)	77.02 (14.61)	78.63 (14.86)	$p= 0.45$
	Social relationships	83.16 (14.41)	83.46 (14.84)	83.91 (13.01)	$p=0.97$
	Environmental	85.87 (12.55)	86.08 (12.72)	82.74 (12.76)	$p= 0.19$
	General QoL	82.90 (16.46)	84.97 (13.08)	85.80 (13.66)	$p= 0.52$
† No statistically significant differences between groups for the whole questionnaire or for any of the subscales					

Table 21: Study outcomes for studies using the Child Health Questionnaire (Psychological well-being subscale)

Observational studies									
Mean score (SD)									
Author (year)		Subscale	T1		T1		T2		Significance
			All treatment group	Treatment group who returned T2 data only	All controls	Controls who returned T2 data only	Treatment group	Control	
			(n=98)	(n=74)	(n=101)	(n=44)	(n=74)	(n=44)	
17	Agou <i>et al.</i> (2011)	Psychological well-being	80.66 (10.09)	79.78 (9.29)	78.33 (12.98)	78.05 (11.7)	81.68 (10.52)	78.84 (13.39)	No statistically significant differences found following treatment in patients compared with controls

- **The Oral Aesthetic Subjective Impact Scale (OASIS) (Table 22):**
-

Randomised Controlled Trials (RCTs):

One RCT reported the use of this scale (Mandall *et al.*, 2010; 2012).

The scores at T1 were similar for both treatment and control groups (20.6 and 20.7 respectively) and scores at T2 reduced for the treatment group, indicating less concern (mean scores 16.9 and 21.0 for the treatment and control groups). The authors concluded that there was a statistically significant reduction in concern about dental appearance for the treatment group compared with the control group ($p=0.003$) between T1 and T2. However, at T3, the regression analysis showed the differences were not significant. It is, however, important to note that the sample size calculation in this study was based on PAR rather than the OASIS score and it is therefore difficult to establish if the study had adequate power.

Observational studies:

A cross-sectional study by Mandall *et al.* (1999) investigated the influence of orthodontic treatment on the perceived oral aesthetic impact of malocclusion. A total of 334 adolescents were randomly selected from schools in Manchester and were classified according to their orthodontic treatment experience and need: group 1 had already received treatment, group 2 had no treatment and an IOTN-DHC score of 1 to 3, and Group 3 had no treatment and an IOTN-DHC score of 4 or 5. The authors reported that there was no statistically significant difference between the groups for the OASIS questionnaire, when a Bonferroni correction was applied. The limitations of cross-sectional studies must be considered though.

Table 22: Study outcomes for studies using Oral Aesthetic Subjective Impact Scale (OASIS)

Randomised Controlled Trials (RCTs)									
Mean Total score (SD)									
Author (year)			T1		T2		T3		Significance
			Treatment	Control	Treatment	Control	Treatment	Control	
7 & 8	Mandall <i>et al.</i> (2010, 2012)	2010	20.6 (6.7)	20.7 (7.4)	16.9 (4.7)	21.0 (6.6)	-	-	<i>p</i> =0.003 between the two groups at T2. Significantly reduced impact of malocclusion in patients in the treatment group at T2.
		2012	20.8 (6.6)	20.7 (7.6)	16.9 (4.4)	22.1 (7.3)	18.3 (5.2)	22.5 (8.3)	Although OASIS scores at T3 tended towards a reduced impact of malocclusion (Treatment Gp. -2.0 points and Control Gp. + 1.4 points), this was not statistically significant in the regression analysis
Observational studies									
			Group 1 (Had treatment)	Group 2 (No treatment and IOTN-DHC score 1 to 3)		Group 3 (No treatment and IOTN-DHC score 4 or 5)		Significance	
13	Mandall <i>et al.</i> (1999)		13.5 (5.8)	11.9 (5.0)		14.2 (5.2)		No statistically significant difference between groups (Bonferroni correction applied)	

- **Childhood Experience Questionnaire (Table 23):**

Randomised Controlled Trials (RCTs):

O'Brien *et al.* (2003) utilised the Childhood Experience Questionnaire in their study to investigate psychosocial benefits associated with early orthodontic treatment with a Clark Twin-block appliance. Regression analysis showed that the only variable (other than baseline data) to have an effect on the questionnaire score was treatment, with a score reduction of 2 points for the treatment group. Therefore, the authors concluded that children who received early orthodontic treatment had statistically fewer negative social experiences ($p=0.033$) than those who did not receive treatment.

Observational studies:

No observational studies reported the use of this scale.

Table 23: Study outcomes for studies using the Childhood Experience Questionnaire

Randomised Controlled Trials (RCTs)								
Mean total score (95% CI)								
Author (year)		T1		T2		T3		Significance
		Early treatment	Control	Early treatment	Control	Early treatment	Control	
5	O'Brien <i>et al.</i> (2003)	49.53 (47.58 to 51.49)	47.68 (45.95 to 49.42)	44.99 (43.31 to 46.66)	46.18 (44.66 to 47.70)	-	-	Regression analysis showed that the only variable (other than baseline data) to have an effect was treatment (beta= -2.07 [CI=-4.00 to -0.17]; $p= 0.033$) and the score reduced by 2 points. Therefore, children who received early treatment had more positive scores than those who did not.

- **Oral Health Impact Profile-14 (OHIP-14) (Table 24):**

Randomised Controlled Trials (RCTs):

No RCTs reported the use of the scale.

Observational studies:

Three observational studies reported the use of the OHIP-14 (de Oliveira and Sheiham, 2003; 2004; Arrow *et al.*, 2011; Feu *et al.*, 2013).

The cross-sectional study by de Oliveira and Sheiham (2003; 2004) found that adolescents who had completed orthodontic treatment showed a reduction in oral health impacts compared with those currently undergoing treatment or those who had never had treatment. They showed that adolescents who had never undergone orthodontic treatment had a greater likelihood of showing impacts compared with treated patients (OR=1.39, 95% CI 1.01 to 1.90) as did those who were undergoing treatment (OR=1.85, 95% CI 1.30 to 2.62).

Arrow *et al.* (2011) showed that there was no statistically significant association between occlusal status as adolescents and quality of life in adulthood. The authors concluded that the occlusal status appeared to have a limited association with QoL and psychosocial factors. They reported that having undergone fixed orthodontic treatment did not appear to be significantly associated with OHRQoL, but interestingly it appeared to be negatively associated with self-esteem. However, the limitations of this study have been discussed earlier.

Feu *et al.* (2013) conducted a longitudinal study in Brazil to examine the changes in OHRQoL in adolescents receiving fixed appliance orthodontic treatment in comparison with those who did not receive treatment. Participants completed the OHIP-14 at T1, 1 year later (T2) and 2 years later (T3). The treatment group showed a significant improvement in OHRQoL ($p < 0.001$) whereas there was a significant deterioration in quality of life in the waiting list and school groups ($p < 0.001$ and $p = 0.05$, respectively). Therefore, the authors concluded that fixed orthodontic treatment in adolescents resulted in significantly improved OHRQoL after 2 years. Whilst acknowledging these findings, it is important to recognize that 34 participants

were lost to follow-up in this study (17 from the waiting list group) but the authors did not report if they felt the drop-outs affected the study.

Summary:

Two of the studies which used the OHIP-14 found that adolescents who had completed orthodontic treatment reported significantly fewer oral health impacts than those currently under treatment or those who had never had treatment (de Oliveira and Sheiham, 2003; 2004). In contrast, the other study found that fixed orthodontic treatment did not appear to be significantly associated with OHRQoL and, surprisingly, it appeared to be negatively associated with self-esteem (Arrow *et al.*, 2011). This study did have some limitations however including no sample size calculation, no baseline data reported and a high loss to follow-up.

Table 24: Study outcomes for studies using the Oral Health Impact Profile-14 (OHIP-14)

Observational studies									
Number of patients (percentage of patients) with impacts scored on OHIP-14									
Author/year		Subscales	Group 1		Group 2		Group 3		Significance
			Treated		Undergoing treatment		Untreated		
1 & 2	de Oliveira and Sheiham (2003; 2004)	Impact	78 (30.2%)		167 (46.8%)		476 (44.9%)		Adjusted values: Treated $p=0.002$ Undergoing treatment $p=0.001$ Untreated $p=0.043$ Adolescents who had never had orthodontic treatment and those who were undergoing treatment were significantly more likely to report one or more dental impacts than those who had undergone orthodontic treatment
		No impact	180 (69.8%)		190 (53.2%)		584 (55.1%)		
Mean scores									
			T1		T2		T3		Significance
			Treatment Group	Community group	Treatment group	Community group	Treatment group	Community group	
18	Arrow <i>et al.</i> (2011)		-	-	-	-	1.63 (SE=0.11)	1.82 (SE=0.24)	$p=0.47$ (NS) No significance difference between treatment and community groups at T3

Median scores												
			T1			T2			T3			Significance
			Treatment Group	Control Group		Treatment Group	Control Group		Treatment Group	Control Group		
				Waiting Group	School Group		Waiting Group	School Group		Waiting Group	School Group	
20	Feu <i>et al.</i> (2013)		9.5	10	4	8	10	5	0	11	5	Treatment group had a significant reduction in OHIP-14 scores ($p<0.001$). Waiting list group and School group showed increased OHIP scores - indicating poorer OHRQoL ($p<0.001$ and $p=0.05$ respectively).

- **Oral Impact on Daily Performances (OIDP) (Table 25):**

Randomised Controlled Trials (RCTs):

No RCTs reported the use of this scale.

Observational studies:

One cross-sectional study by de Oliveira and Sheiham (2003; 2004) reported the use of the OIDP in a study of Brazilian adolescents. Multiple regression showed that adolescents who had never undergone orthodontic treatment had more oral health impacts than those who were currently undergoing treatment or who had completed treatment. A statistically significant difference was also reported for the 'smiling, laughing and showing teeth without embarrassment' subscale ($p < 0.001$).

Additionally, the results of the adjusted odds ratio showed that untreated adolescents were 1.43 times more likely to report dental impacts than treated adolescents and those who were undergoing orthodontic treatment were 1.84 times more likely to have impacts than those who had completed treatment. After adjusting for all other explanatory variables, orthodontic treatment status remained statistically significant ($p = 0.008$). The relationship between age and overall oral health impact was also assessed and found to be significant ($p = 0.048$). Younger adolescents (15 years old) were 1.27 times more likely to have oral impacts than those aged 16 years and females reported 1.25 times more dental impacts than males. The authors concluded that participants who completed orthodontic treatment had better OHRQoL than those currently under treatment or those who had never had treatment.

Table 25: Study outcomes for studies using the Oral Impact on Daily Performances (OIDP)

Observational studies						
Number of patients (Percentages of patients with impacts scored on OHIP-14)						
Author (year)			Group 1	Group 2	Group 3	Significance [†]
			Treated	Undergoing treatment	Untreated	
1 & 2	de Oliveira and Sheiham (2003; 2004)	Impact	58 (22.5%)	128 (35.9%)	363 (34.2%)	Adjusted values: Treated $p=0.008$ Undergoing treatment $p=0.002$ Untreated $p=0.045$
		No impact	200 (77.5%)	229 (64.1%)	697 (65.8%)	
		Subscale scores (Mean Rank of reported impacts- from bivariate analysis)				
2	de Oliveira and Sheiham (2004)	Eating	820.10	838.05	842.34	0.584
		Speaking	807.86	837.21	845.60	0.062
		Cleaning teeth	826.50	846.17	838.05	0.234
		Sleeping	835.50	840.20	837.87	0.448
		Smiling, laughing, etc	768.17	830.70	857.46	0.001
		Emotional stability	836.18	833.50	839.96	0.528
		Social activities	836.50	836.50	838.87	0.418
		Contact with people	840.01	833.50	839.03	0.286
		Sport	836.50	841.19	837.29	0.151
		† Adolescents who had never had orthodontic treatment reported more oral health impacts than those who were undergoing treatment or had completed treatment. A statistically significant difference was found between the three groups regarding: “smiling, laughing and showing teeth without embarrassment”.				

- **KINDL Questionnaire (Table 26):**

Randomised Controlled Trials (RCTs):

No RCTs reported the use of the questionnaire.

Observational studies:

One cross-sectional study conducted by Schmidt *et al.* (2008) examined the impact of orthodontic treatment on QoL in a large orthodontic practice. Two independent groups of patients completed questionnaires: before (Group 1) and after treatment (Group 2). The KINDL questionnaire was used to assess QoL alongside other clinical and social measures. Results were presented graphically only, but the text suggests no statistically significant differences in QoL between the pre- (mean score 78) and post-treatment (mean score 74). The study was translated by a native German speaker (Dr Dirk Bister) and no p-values were identified in the translation for the total questionnaire score or the subscale scores.

Table 26: Study outcomes for study using the KINDL questionnaire

Observational studies					
Mean scores (estimated from the graphs included in the paper)					
Author (year)		Total and Subscales	Group 1	Group 2	Significance
			Pre-treatment	Post- treatment	
14	Schmidt <i>et al.</i> (2008)	Total	78	74	No p-values were identified in the translation for the questionnaire, results were presented graphically only. The text suggests no statistically significant differences between groups.
		Subscale scores			
		Physical well-being	82	74	As above
		Psychological well-being	84	82	As above
		Self-Worth	Not included on the graph	Not included on the graph	Not included on the graph
		Family	83	81	As above
		Friends	82	80	As above
		Everyday Functioning (School etc)	72	64	As above

- **Summary of all data for questionnaires used in the Kenealy and Shaw study from the longitudinal Cardiff study (Table 27):**
-

Observational studies:

The longitudinal observational study by Kenealy *et al.* and Shaw *et al.* (2007) reported on the so-called 'Cardiff study'. Kenealy *et al.* (2007) reported the data for two groups: participants who had no orthodontic treatment and those who underwent orthodontic treatment prior to T3. Shaw *et al.* (2007) divided the no orthodontic treatment group into two groups: Group 1 (who needed treatment in 1981) and Group 2 (with no treatment need in 1981) and those who underwent treatment into two groups also: Group 3 (who needed treatment in 1981) and Group 4 (with no treatment need in 1981).

At T3, those participants who had undergone orthodontic treatment reported better dental alignment and greater satisfaction with life than those who had no treatment. Statistically significant differences also existed for self-esteem ($p=0.005$), Satisfaction with Life ($p=0.016$) and certain items of the WHOQoL-BREF scale ($p=0.011$). However, when the data were analysed with self-esteem at T1 as a covariate, the self-esteem difference between groups was no longer significant. The authors concluded that lack of orthodontic treatment, when there was a prior need for treatment, did not appear to lead to psychological difficulties later in adulthood.

The limitations of the study must, however, be borne in mind. These include the very high loss to follow-up, the lack of a sample size calculation and the use of questionnaires at T3 which were not included at T1. These factors all limit the conclusions which can be drawn.

Table 27: Summary of data for questionnaires used in the Kenealy *et al.* (2007) and Shaw *et al.* (2007) publications from the longitudinal Cardiff study

Observational studies									
Mean scores (SD)									
Author (year)		Scales	Shaw <i>et al.</i> (2007)				Kenealy <i>et al.</i> (2007)		Significance
			T3 (20 yr follow-up)				T3 (20 yr follow-up)		
			No orthodontic treatment (n= 181)		Received orthodontic treatment (n=150)		No treatment (n=182)	Treated (n=150)	
			Group 1 (Need in 1981)	Group 2 (No need in 1981)	Group 3 (Need in 1981)	Group 4 (No need in 1981)	2001	2001	
3 & 4	Kenealy <i>et al.</i> (2007), Shaw <i>et al.</i> (2007)	Psychological health							
		General Health Questionnaire (GHQ-12)	2.01 (2.83)	1.51 (2.38)	1.70 (2.29)	1.67 (2.02)	1.87 (2.70)	1.70 (2.26)	Shaw <i>et al.</i> (2007) study: <i>p</i> =NS between the 4 subgroups at T3
									Kenealy <i>et al.</i> (2007) study: <i>p</i> = NS (between no treatment and treated groups at T3)
		Rosenberg Self-Esteem Scale	31.40 (4.83)	31.63 (4.84)	32.99 (4.25)	32.25 (5.41)	31.50 (4.82)	32.93 (4.34)	Shaw <i>et al.</i> (2007) study: <i>p</i> =0.014 (between groups 1 and 3)

									Kenealy et al. (2007) study: $p=0.005$ (between no treatment and treated groups at T3)
		Centre for Epidemiological studies Depression Scale (CES-D)	11.30 (10.00)	10.75 (9.35)	9.36 (7.80)	10.33 (10.40)	11.13 (9.75)	9.44 (8.00)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: $p=NS$ (between no treatment and treated groups at T3)
		Perceived Stress Scale (PSS) Scale	22.79 (7.77)	22.39 (7.26)	21.71 (6.34)	21.33 (7.29)	22.64 (7.58)	2.68 (6.39)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: $p=NS$ (between no treatment and treated groups at T3)
		Satisfaction With Life Scale (SWLS)	22.85 (7.55)	24.30 (6.89)	25.07 (6.12)	26.33 (6.51)	23.34 (7.36)	25.17 (6.13)	Shaw et al. (2007) study: $p=0.032$ (group 1 and 3 at T3)
									Kenealy et al. (2007) study: $p=0.016$ (between no treatment and treated groups at T3)

									T3)	
		Health Related Quality of Life								
		WHOQoL-BREF (Total)	4.05 (0.76)	4.05 (0.69)	4.25 (0.65)	4.25 (0.62)	4.05 (0.74)	4.25 (0.64)	Shaw et al. (2007) study: $p= 0.048$ (between groups 1 and 3)	
									Kenealy et al. (2007) study: $p= 0.011$ (between no treatment and treated groups at T3)	
		WHOQoL-BREF (Subscales)	Physical domain	16.32 (2.48)	16.47 (2.24)	17.09 (1.50)	16.71 (1.40)	16.38 (2.40)	17.06 (1.77)	Shaw et al. (2007) study: T1: $p=0.012$ (between groups 1 and 3)
										Kenealy et al. (2007) study: $p= 0.004$ (between no treatment and treated groups at T3)
			Psychological domain	14.44 (2.58)	14.75 (2.53)	15.30 (1.96)	14.83 (2.13)	14.54 (2.56)	15.26 (1.97)	Shaw et al. (2007) study: $p=0.011$ (between groups 1 and 3 at T3)
										Kenealy et al. (2007) study: $p=0.005$ (between no treatment and

										treated groups at T3)
			Environment domain	14.45 (1.98)	15.09 (1.97)	15.16 (1.92)	14.71 (2.07)	14.65 (1.99)	15.13 (1.93)	Shaw et al. (2007) study: T3: $p=0.008$ (between groups 1 and 3)
										Kenealy et al. (2007) study: T3: $p=0.029$ (between no treatment and treated Gp. at T3)
			General health facet	3.70 (0.97)	3.79 (0.84)	3.91 (0.91)	3.67 (0.89)	3.73 (0.93)	3.89 (0.91)	Shaw et al. (2007) study: NS between the subgroups
										Kenealy et al. (2007) study: T3: $p= NS$ (between no treatment and treated groups at T3)
			Social relationships domain	14.79 (3.34)	15.36 (3.37)	15.69 (3.11)	14.22 (3.18)	14.97 (3.35)	15.57 (3.13)	Shaw et al. (2007) study: NS between the subgroups
										Kenealy et al. (2007) study: T3: $p= NS$ (between no treatment and treated groups at T3)

		Iowa-Netherlands Comparison Orientation (I-NCOM)	34.20 (7.76)	34.02 (7.39)	32.59 (7.64)	331.17 (7.04)	34.19 (7.63)	32.47 (7.58)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=0.042$ (between no treatment and treated groups at T3) ²¹
		Social Interaction Anxiety	23.65 (14.54)	22.09 (12.13)	221.16 (12.57)	23.50 (13.51)	23.13 (13.78)	21.35 (12.62)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=NS$ (between no treatment and treated Gp. at T3) ²¹
		Social phobia	13.46 (12.65)	13.84 (13.03)	11.40 (10.93)	11.67 (8.44)	13.59 (12.70)	11.42 (10.73)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=NS$ (between no treatment and treated groups at T3)

		Self efficacy	30.35 (4.91)	30.54 (4.17)	30.78 (4.31)	30.92 (4.32)	30.41 (4.66)	30.79 (4.29)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)
		Life events	259.4 (173.4)	230.3 (131.8)	260.7 (144.8)	205.2 (105.3)	249.33 (161.7)	256.26 (142.6)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)
		Value attached to health	20.06 (4.48)	20.19 (4.92)	19.93 (4.23)	21.25 (3.70)	20.12 (4.60)	20.04 (4.20)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)

		Belief in dental health	18.95 (3.79)	18.82 (3.36)	18.53 (4.02)	19.17 (3.29)	18.88 (3.67)	18.58 (3.96)	Shaw et al. (2007) study: NS between the subgroups Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)
		SF-36							
		General health perception	72.78 (18.03)	74.59 (16.34)	78.28 (16.13)	80.58 (10.64)	73.45 (17.49)	78.46 (15.74)	Shaw et al. (2007) study: T3: $p=0.031$ (Between groups 1 and 3) Kenealy et al. (2007) study: T3: $p= 0.007$ (between no treatment and treated groups at T3)
		Reported health transition	3.28 (0.79)	3.12 (0.71)	3.18 (0.59)	3.00 (0.43)	3.24 (0.77)	3.17 (0.59)	Shaw et al. (2007) study: NS between the subgroups Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)

		Physical functioning	92.12 (15.74)	91.31 (16.57)	93.45 (14.01)	92.50 (13.23)	91.91 (15.93)	93.37 (13.90)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)
		Role physical-limitations	90.02 (18.76)	91.89 (18.86)	92.51 (15.02)	86.46 (25.39)	90.66 (18.72)	92.02 (16.07)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=$ NS (between no treatment and treated groups at T3)
		Bodily pain	79.48 (22.92)	79.96 (23.01)	84.99 (17.76)	82.33 (24.96)	79.74 (22.87)	84.78 (18.36)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=0.031$ (between no treatment and treated groups at T3)
		Vitality	60.50 (18.49)	57.86 (18.72)	61.58 (15.53)	57.29 (20.09)	59.75 (18.54)	61.23 (15.90)	Shaw et al. (2007) study: NS between the subgroups T3: $p=$ NS (between no treatment and treated groups at T3)

		Social function	82.46 (21.44)	85.09 (22.59)	88.42 (18.61)	87.50 (23.23)	82.24 (21.73)	88.34 (18.94)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=0.025$ (between no treatment and treated groups at T3)
		Role emotional-limitations	88.58 (18.63)	89.77 (14.94)	91.67 (14.49)	95.83 (9.73)	88.97 (17.47)	92.00 (14.18)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=NS$ (between no treatment and treated groups at T3)
		Mental health	73.42 (16.45)	73.59 (15.72)	75.71 (14.76)	76.25 (17.34)	73.51 (16.14)	75.75 (14.92)	Shaw et al. (2007) study: NS between the subgroups
									Kenealy et al. (2007) study: T3: $p=NS$ (between no treatment and treated groups at T3)

2.3.3 Meta-analysis:

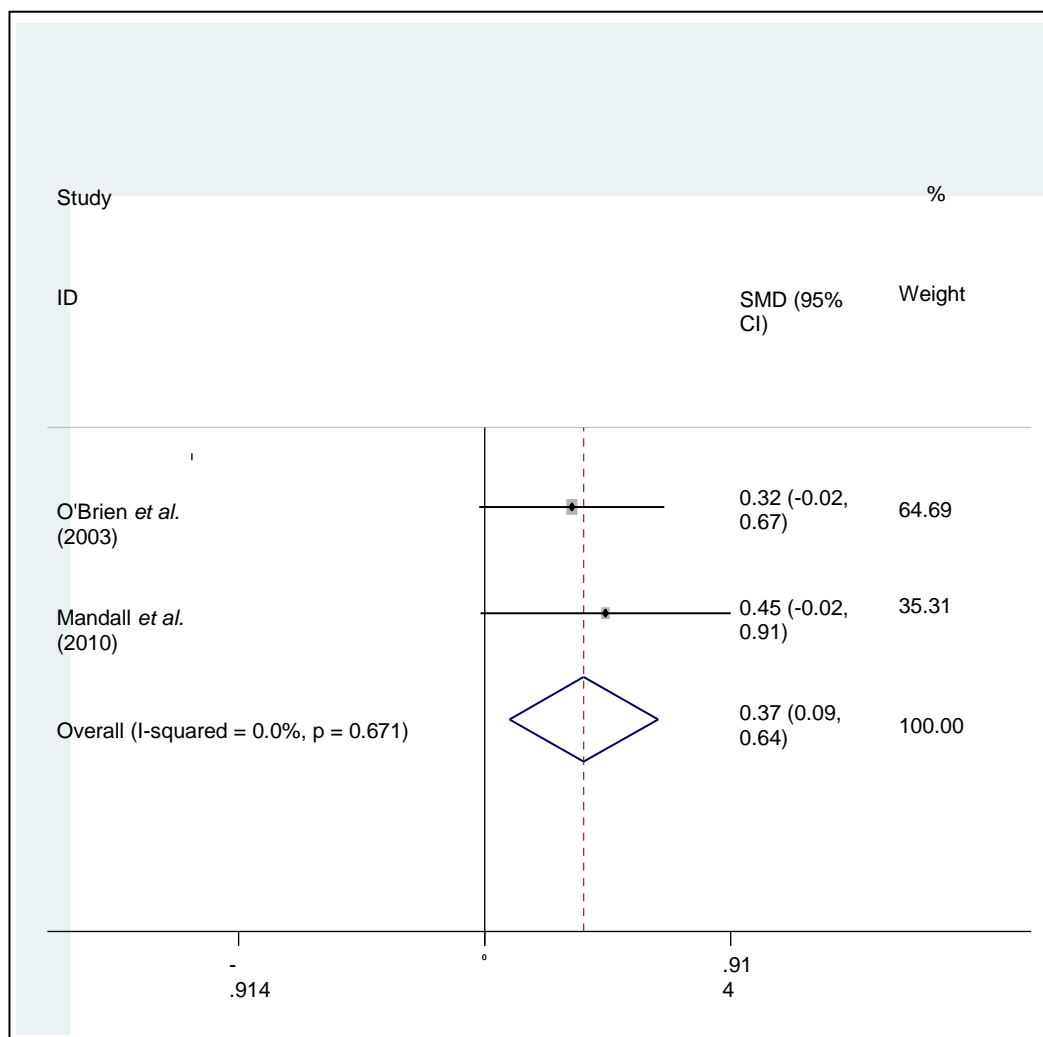
A meta-analysis was used to explore the Piers-Harris Self-Concept data, the most commonly used questionnaire in the RCTs in this review. Two studies were included (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012), while the other two studies were excluded because of a lack of complete data (Dann *et al.*, 1995) and a design which was too complex to include in the meta-analysis (Korabik, 1994). There are some limitations to this meta-analysis because both Class II and Class III studies were combined and these limitations will be discussed later in the review.

The meta-analysis was undertaken using Stata 12 and it was the differences between the treatment and control/untreated groups at T2 and T3 which were investigated. This did not account for baseline scores, which is a limitation. In order to reduce the problems associated with this, the T1 scores for the treatment and control groups were compared and there were no statistically significant differences between them (Table 28).

	Mean scores (SD) at T1		p-value
	Treatment	Control	
O'Brien <i>et al.</i> (2003)	n=64	n=68	0.9177 (ns)
	58.37 (11.0) [†]	58.17 (11.17) [†]	
O'Brien <i>et al.</i> (2009)	n=62	n=70	0.5039 (ns)
	60.33 (11.99)	61.78 (12.86)	
Mandall <i>et al.</i> (2010)	n=35	n=38	0.2633 (ns)
	51.0 (7.3)	48.9 (8.6)	
	n=30	n=33	0.8321 (ns)
Mandall <i>et al.</i> (2012)	50.3 (6.8)	49.9 (8.1)	
The SD was calculated from the 95% CIs given in the paper			

Table 28: T1 data for those studies included in the meta-analysis

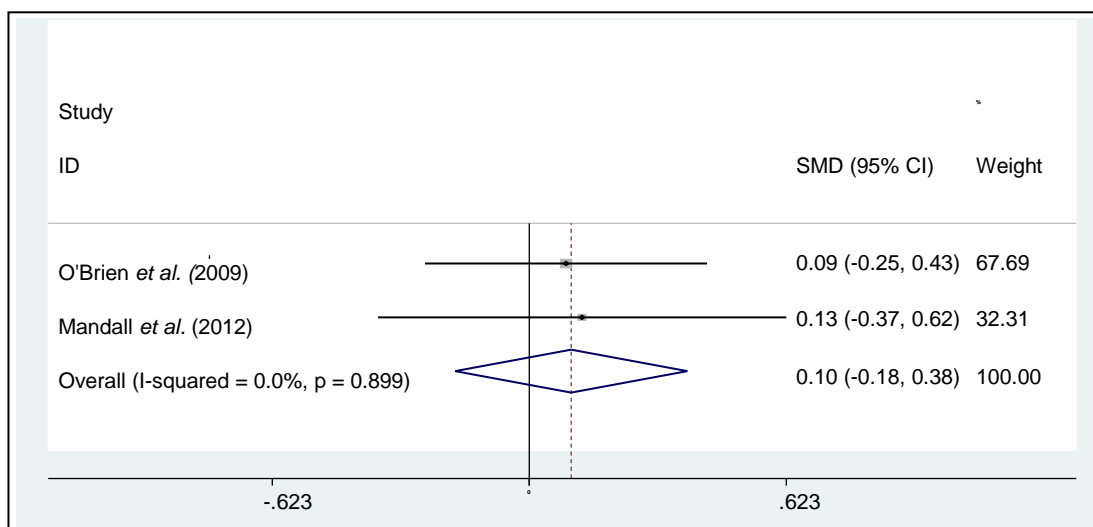
The meta-analysis was performed using means and SDs. As the O'Brien *et al.* (2003) paper reported 95% CIs rather than SDs, the SDs first had to be calculated.



Heterogeneity chi-squared= 0.18 p=0.671
 I-squared (variation in SMD attributable to heterogeneity)=0.0%
 Test of SMD=0: Z= 2.61 p=0.009

Figure 5: Forest plot depicting SMD and 95% CI for the Piers-Harris Self-Concept scale after the first phase of treatment

Figure 5 shows that the Standardised Mean Difference (SMD) was 0.37 (95% CI: 0.09 to 0.64) and the p-value was 0.009, indicating a statistically significant difference in self-concept between the treatment and control groups after the first phase of orthodontic treatment, and this suggests potentially beneficial effects of early treatment at that time point.



Heterogeneity chi-squared= 0.02 $p=0.899$
 I-squared (variation in SMD attributable to heterogeneity =0.0%
 Test of SMD=0: Z= 0.71 $p=0.478$

Figure 6: Forest plot depicting SMD and 95% CI for the Piers-Harris Self-Concept Scale for studies after the second phase of treatment

Figure 6 shows the standardised mean difference (SMD) was 0.10 (95% CI: -0.18 to 0.38) with a p-value of 0.478, indicating no significant difference between the treatment and control groups at T3. This suggests that neither treatment modality was significantly better than the other in terms of enhancing self-concept in the longer term. It does not however indicate whether or not orthodontic treatment is effective in enhancing self-concept as both groups had undergone treatment at that stage.

2.3.4 Quality assessment and risk of bias (Table 29-32):

Quality assessment for the Randomised Controlled Trials (Table 30):

The results of the quality assessment for the four RCTs are shown in Table 30. The assessment showed that all of the studies were judged to be at overall high risk of bias.

The two researchers evaluated the studies and “other bias” was considered to be high if a sample size calculation was not undertaken or if it was undertaken based on outcomes other than QoL or psycho-social outcomes. Therefore, a retrospective power calculation for studies included in the meta-analysis (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) was performed using G*Power software (<http://www.softpedia.com/get/Science-CAD/G-Power.shtml>) to determine whether the power was adequate for the psychosocial outcome (Table 29). Power calculations were undertaken for a two-sample t-test statistical set-up. A clinically relevant difference for the pre- to post-treatment Piers-Harris Self-Concept Scale was set as 5 points for all power calculations.

	Sample size recruited	Significance level	Calculated power	Results
O'Brien <i>et al.</i> (2003)	Treatment group: 65 Control group: 70	0.05%	75%	Potentially underpowered to detect differences if they existed
O'Brien <i>et al.</i> (2009)	Treatment group: 62 Control group: 70	0.05%	90%	Adequate power to detect differences if they existed
Mandall <i>et al.</i> (2010)	Treatment group: 35 Control group: 38	0.05%	75%	Potentially underpowered to detect differences if they exist
Mandall <i>et al.</i> (2012)	Treatment group: 30 Control group: 33	0.05%	70%	Potentially underpowered to detect differences if they existed

Table 29: Retrospective power calculation for the O'Brien *et al.* (2003,2009) and Mandall *et al.* (2010, 2012) studies

All calculations were based on the differences in the end-of-treatment scores between the two groups, with the assumption that the pre-treatment scores for the two groups were similar. For the O'Brien *et al.* (2003) study, the 95% CIs were quoted, therefore standard errors were calculated by approximation and then, with the sample size the authors gave in the paper, standard deviations of the post-treatment scores were calculated. Based on the sample sizes of 65 and 70 and a significance level of 0.05, the power was 75%, which suggests that the study may be slightly underpowered, but it must be noted that this did involve assumptions to calculate the SD used. The calculation for the O'Brien *et al.* (2009) publication used post-treatment SDs for both groups and the sample sizes of 62 and 70 with a significance level of 0.05%. The power calculated was 90%, therefore, the O'Brien *et al.* (2009) study appeared to have adequate power to detect differences if they existed.

A power calculation for the Mandall *et al.* (2010) study used the post-treatment SD for both groups, sample sizes of 35 and 38 and a significance level of 0.05%. The power was calculated as 75%. For the three-year follow-up study (Mandall *et al.*, 2012), the power was calculated as 70%. Therefore, the Mandall *et al.* study would appear to be potentially underpowered to detect differences for the Piers-Harris Scale if they existed.

Management of confounders:

This systematic review did include some well-controlled studies which accounted for confounders in the methodology and statistical analysis. RCTs have the ability to control for confounders by allowing random allocation of participants into groups, therefore, it is hoped that confounders were equally distributed between the two groups in the RCTs included. There is always a possibility that this distribution was not equal and the authors accounted for this to some extent by the statistical analyses used. O'Brien *et al.* (2003) reported the use of a regression analysis at T2 which controlled for self-concept scores at baseline. From this analysis they found that self-concept scores in the early treatment group had improved significantly compared with the control group ($p=0.013$).

The T3 regression models also controlled for treatment centre, age at baseline, age at the start of the second stage of the study, gender, socio-economic status (Carstairs' score) and baseline values (when appropriate). The results showed no

significant difference in self-concept between those who had early treatment and those who had treatment in adolescence (O'Brien *et al.*, 2009). It is important to note that the conclusions therefore relate to a comparison of the effect related to treatment timing and not whether orthodontic treatment affects self-concept *per se*.

In the Mandall *et al.* study (2010; 2012), multiple linear regression models were fitted to the dependent variable at T2, with T1 data and group as covariates. Similarly, at T3, multiple linear regression models were fitted to the dependent variable with T1 data and group as covariates.

Dann *et al.* (1995) included age, gender, overjet, Irregularity Index, SNA and SNB as variables in the regression models. Regression analysis was used for the total self-concept score and also the subscale scores. A Spearman correlation was used to study the correlation between change in overjet resulting from early treatment and change in self-concept score and the authors concluded that these correlations were not statistically significant (*r* values ranged from -0.1 to 0.20).

Albino *et al.* (1994) included the Crandall Social Desirability Scale as a covariate and they used the Treatment Priority Index as a measure of severity of malocclusion and reported it at baseline to confirm comparability between groups regarding treatment need.

Quality assessment for the observational studies (Table 31):

A modified version of the Newcastle-Ottawa Scale (NOS) was used to assess quality in the observational studies. There was some variation between the two examiners in reporting selection, comparability and outcome bias but all studies were judged as having an overall high risk of bias according to this scale.

Regarding selection bias, a high risk of bias was reported if a sample size calculation was not reported or was not based on QoL/psychosocial outcomes. Nine studies did not report a sample size calculation and the sample size calculation was based on psychosocial outcomes in only four of the included studies. One study based the calculation on the prevalence of oral health impacts (de Oliveira and Sheiham, 2003; 2004) and another based it on the OASIS score (Mandall *et al.*, 1999). Feu *et al.* (2013) undertook their sample size calculation based on OHIP-14

scores and Benson *et al.* (2015) undertook a sample size calculation based on the CPQ 11-14 scores published in a previous study (O'Brien *et al.*, 2006).

Management of confounders:

There was marked variation between the observational studies in terms of accounting for the confounders; some studies did not report consideration of confounders (Mandall *et al.*, 1999; Birkeland *et al.*, 2000; Taylor *et al.*, 2009) whereas others did discuss this.

Agou *et al.* (2011) reported the use of ANCOVA to explore group differences; model 1 controlled for age, Dental Aesthetic Index (DAI) and baseline scores, while model 2 controlled for all variables in model 1 and also psychological well-being. Model 1 aimed to address whether there was a difference in OHRQoL between the treatment and control groups having accounted for age and DAI scores, while model 2 aimed to address if there was a difference in OHRQoL between the treatment and control groups having controlled for PWB.

In the Kenealy *et al.* (2007) and Shaw *et al.* (2007) longitudinal studies, self-esteem at baseline was controlled for. Korabik (1994) reported that the effect of maturation due to age was not controlled for in their study, so compared the participants with the age-specific norms for the Piers-Harris Self-Concept Scale. Multivariate analysis of variance (MANOVA) was also carried out using the six subscales of the Piers-Harris scale as dependent variables. The authors analysed the physical appearance subscale score using ANOVA because they predicted the use of these scores would improve as a function of treatment. In all of these analyses, the authors used patient age and duration of treatment as covariates and they concluded that these two covariates did not appear to significantly affect self-esteem.

The study by de Oliveira and Sheiham (2003; 2004) used multiple regression to investigate the relationship between orthodontic treatment and overall oral health impact. The authors included potential confounders (age, gender, social class, DHC-IOTN) in the regression analysis and interactions between variables were also explored.

Arrow *et al.* (2011) used bivariate analyses for the Oral Health Impact, Satisfaction With Life and self-esteem at follow-up with baseline. Analysis of variance and

multivariate analyses using linear regression were performed to determine the effects of various factors on the psychological outcomes. In the Mandall *et al.* (1999) study, the authors accounted for gender, ethnicity and social deprivation. They concluded that these factors did not influence a child's self-perceived AC scores or self-perceived need for orthodontic treatment. Thus, OASIS scores were not affected.

Schmidt *et al.* (2008) reported that they adjusted for the variables using MANOVA. However, there was no information regarding which variables the authors accounted for and how they undertook the analysis.

Quality assessment using the GRADE system (Table 32):

The GRADE system was used to assess both the RCTs and observational studies. In the RCTs, the ratings were very low, low and moderate. Only two studies were assessed as having moderate quality (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012). These studies were both randomised controlled trials which were downgraded from high to moderate quality rating because of the inability to blind patients to the intervention. It must however be noted that this is unavoidable in orthodontics so the study quality was probably as high as achievable. One RCT was recorded as low quality as psychological data were not collected from the start of the RCT for all patients (Dann *et al.*, 1995). One trial was assessed as very low quality and was downgraded because malocclusion types were not reported and there was a perceived heterogeneity due to different treatment methods (Albino *et al.*, 1994).

Regarding the observational studies, five studies were considered as low quality and eight studies as very low. The Korabik (1994) study was assessed as very low quality due to the complex and difficult methodology and in one subgroup there was a very small sample size (n=12). The longitudinal studies by Arrow *et al.* (2011) and Kenealy *et al.* (2007) and Shaw *et al.* (2007) were classified as very low due to the large losses to follow up. Two studies were considered as very low because insufficient data was presented; the Schmidt *et al.* (2008) study had inadequate data presented and had to be interpreted from graphs. Similarly, the Badran (2010) study did not report actual data and the findings had to be interpreted from the text.

Summary of quality assessment and risk of bias:

Overall, all RCTs and observational studies showed a high risk of bias. In the RCTs, the inability to blind patients and clinicians to the group allocation was associated with a high risk of bias when reporting the quality assessment, but there is no obvious way to avoid this in such clinical studies so two studies showed close to the highest quality achievable under these circumstances. Importantly, the two RCTs which were well conducted did not base the sample size calculation on psychosocial measures and this was the main aspect of the methodology which could have been improved (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012).

Sample size calculations were based on psychosocial measures in only four studies (Mandall *et al.*, 1999; de Oliveira and Sheiham, 2003; 2004; Feu *et al.*, 2013; Benson *et al.*, 2015) and this therefore introduced a risk of bias in most studies.

In summary, only two RCTs were considered as having moderate rating and the ratings for the rest of the studies were low or very low.

Impact of study quality:

Heterogeneity:

Marked heterogeneity was found between studies in terms of differences in the psychosocial and QoL outcome measures used, types of malocclusions included and types of orthodontic treatment undertaken. These factors meant that meta-analyses were generally not appropriate. However, it was felt that it was appropriate to undertake a meta analysis of the Piers-Harris Self-concept data for two of the RCTs, despite the heterogeneity involved in including a Class II and a Class III studies. The limitations of this will be discussed further in the next section.

The heterogeneity of questionnaires used is of concern and highlights the need for an agreed set of outcome measures specifically for orthodontic treatment (Tsichlaki and O'Brien, 2014). Additionally, only one of the questionnaires (OASIS) was developed specifically for malocclusion/ orthodontic treatment and this highlights the need for an outcome measure specific to orthodontics.

Table 30: Quality assessment for RCTs using the Cochrane Collaboration tool for assessing risk of bias (as described in the Cochrane Handbook for Systematic Reviews of interventions (Higgins and Green, 2011))

Quality assessment for RCTs															
No	Author/s year	Selection bias		Performance bias ††		Detection bias		Attrition bias		Reporting bias		Other bias †		Overall bias	
		HMA	SJC	HMA	SJC	HMA	SJC	HMA	SJC	HMA	SJC	HMA	SJC	HMA	SJC
3	O'Brien <i>et al.</i> (2003)	Low	Low	High	High	Unclear	Unclear	Low	Low	Low	Low	High	High	High	High
4	O'Brien <i>et al.</i> (2009)	Low	Low	High	High	Unclear	Low	Low	Low	Low	Low	High	High	High	High
7	Mandall <i>et al.</i> (2010)	Low	Low	High	High	Low	Low	Low	Low	Low	Low	High	High	High	High
8	Mandall <i>et al.</i> (2012)	Low	Low	High	High	Low	Low	Low	Low	Low	Low	High	High	High	High
9	Albino <i>et al.</i> (1994)	Unclear	Unclear	High	High	Unclear	Unclear	Low	Low	Low	Low	High	High	High	High
11	Dann <i>et al.</i> (1995)	Unclear	Unclear	High	High	High	High	High	High	Low	Low	High	High	High	High
† Based on the sample size calculation – the calculation was undertaken based on dental outcomes not psycho-social outcomes for all of the studies in this table. † † Largely based on an inability to conceal group allocation from the clinician or the patient. Gradings are highlighted if there was a difference in classification between the two authors (HMA and SJC).															

Table 31: Quality assessment for observational studies using the modified version of the Newcastle-Ottawa Scale for observational studies

Quality assessment for non-RCTs									
No	Author/s year	Selection bias		Comparability bias		Outcome bias		Overall bias	
		HMA	SJC	HMA	SJC	HMA	SJC	HMA	SJC
1	de Oliveira and Sheiham (2003)	***	***	**	*	**	*	High	High
2	de Oliveira and Sheiham (2004)	***	**	*	*	*	*	High	High
5	Kenealy <i>et al.</i> (2007)	***	***	*	*	**	**	High	High
6	Shaw <i>et al.</i> (2007)	****	***	*	**	**	**	High	High
10	Korabik (1994)	**	**	*	*	**	*	High	High
12	Birkeland <i>et al.</i> (2000)	***	***	**	**	**	**	High	High
13	Mandall <i>et al.</i> (1999)	***	***	**	*	-	-	High	High
14	Schmidt <i>et al.</i> (2008)	**	*	*	*	*	*	High	High
15	Taylor <i>et al.</i> (2009)	**	-	*	*	**	**	High	High
16	Jung (2010)	**	*		*	*	*	High	High
17	Agou <i>et al.</i> (2011)	****	****	*	*	**	**	High	High
18	Arrow <i>et al.</i> (2011)	***	***	*	*	**	**	High	High
19	Badran (2010)	****	***	*	*	*	**	High	High

20	Feu <i>et al.</i> (2013)	****	****	*	*	**	**	High	High
21	Benson <i>et al.</i> (2015)	****	****	*	*	***	**	High	High

Table 32: Quality assessment by the GRADE system

No	Author/year	Quality rating		Agreed rating
		HMA	SJC	
RCTs				
1	O'Brien <i>et al.</i> (2003)	Moderate	Moderate	Moderate
2	O'Brien <i>et al.</i> (2009)	Moderate	Moderate	Moderate
3	Mandall <i>et al.</i> (2010)	Moderate	Moderate	Moderate
4	Mandall <i>et al.</i> (2012)	Moderate	Moderate	Moderate
5	Albino <i>et al.</i> (1994)	Low	Very low	Very low
6	Dann <i>et al.</i> (1995)	Low	Low	Low
Non-RCTs				
1	de Oliveira and Sheiham (2003)	Low	Low	Low
2	de Oliveira and Sheiham (2004)	Low	Low	Low
3	Kenealy <i>et al.</i> (2007)	Very low	Very low	Very low
4	Shaw <i>et al.</i> (2007)	Very low	Very low	Very low
5	Korabik (1994)	Low	Very low	Very low

6	Birkeland <i>et al.</i> (2000)	Low	Low	Low
7	Mandall <i>et al.</i> (1999)	Low	Low	Low
8	Schmidt <i>et al.</i> (2008)	Low	Very low	Very low
9	Taylor <i>et al.</i> (2009)	Low	Low	Low
10	Jung (2010)	Low	Low	Low
11	Agou <i>et al.</i> (2011)	Low	Low	Low
12	Arrow <i>et al.</i> (2011)	Low	Very low	Very low
13	Badran (2010)	Low	Very low	Very low
14	Feu <i>et al.</i> (2013)	Low	Low	Low
15	Benson <i>et al.</i> (2015)	Low	Low	Low

2.4 Discussion:

2.4.1 Statement of key findings:

This systematic review provides evidence about the psychosocial and QoL impacts associated with orthodontic treatment in children and adolescents. As reported, there was great variation in the included studies. Furthermore, there were no studies which were categorised as high quality due to the various methodological issues highlighted. All of which creates a challenge for the review.

These problems prevented the review from having definite conclusions and there was inadequate evidence to either support or refute that orthodontic treatment is associated with psychosocial and QoL benefits in children and adolescents. The problems include: lack of RCTs, differences between comparison groups, heterogeneity of the types of malocclusions within and between studies, heterogeneity of the types of orthodontic treatment within and between studies, loss to follow-up, potential type 1 errors (methodological problems; bias and confounding factors), potential type 2 errors (inadequate sample size), differences in ethnicity/cultural/social aspects, differences in questionnaires used, and some of these questionnaires may also have been insensitive to dental changes or not validated for use with children and adolescents. Each problem will be discussed further in this section.

- **Lack of Randomised Controlled Trials (RCTs):**

RCTs are powerful tools in clinical research. Random allocation in RCTs reduces selection bias by distributing groups of participants into comparable treatment or control groups. Subsequently, both known and unknown confounders should be equally distributed between the groups if the randomisation was effective and any differences in outcome should be explained primarily by the treatment (Evans, 1998). Furthermore, RCTs provide a better chance than observational studies of detecting small or moderate effects.

In orthodontics, there is a lack of high-quality RCTs due to ethical and practical issues. It is considered unethical to delay orthodontic treatment in patients with a

malocclusion. Furthermore, in some clinical studies it is not possible to blind the participants and the clinicians to the group allocation. It has been reported that 'unblinded' RCTs tend to be biased towards beneficial effects (Marson *et al.*, 2007; Wood *et al.*, 2008). With these limitations, there will almost always be a high risk of bias. In this review, all of the RCTs were considered to be at high risk of bias because of the inability to blind the participants and clinicians to the allocation and other forms of bias which will be discussed later (Albino *et al.*, 1994; Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012). However, the O'Brien *et al.* (2003; 2009) and Mandall *et al.* (2010; 2012) studies had good methodology overall and some of the limitations could not be avoided.

- **Differences in comparison/control groups:**

The control group plays a vital role in clinical research; it allows the researcher to reduce confounding variables and bias, so the observed changes are more likely to be due to the treatment itself rather than to other confounding factors. Normal biological variation, researcher bias and environmental variation are all factors that can affect the outcome, thus control groups provide a standard for comparison purposes.

Comparing the control group with the treatment group helps to reduce confounders and therefore reduce bias, but does not eliminate it. In orthodontics, there are potential pitfalls in recruiting participants for a control group and it is difficult to establish an ideal control group due to ethical implications (Pithon, 2013). In the RCTs, control groups were allocated by randomisation of the participants included in the trial, while in the observational studies there was variation between studies regarding how the control groups were recruited.

In this review, two RCTs did use ideal control groups but this was only feasible because they were investigating early treatment and the option was still available for treatment at the conventional time for the control group participants (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012). Two observational studies reported the use of patients from waiting lists as a control group (Agou *et al.*, 2011; Feu *et al.*, 2013). Agou *et al.* (2011) recruited a control group from department waiting lists to control for age-related effects. Similarly, Feu *et al.* (2013) used a control group from waiting lists and also children recruited from local schools. In both studies, the type and

severity of the malocclusion affecting those patients in the control group were not reported. The patients may have had milder malocclusions than the treatment group or may have been younger which was why they were on a waiting list. Albino *et al.* (1994) reported that adolescents who attended the clinic but were denied treatment were invited to participate as a control group. The reasons why these participants were denied treatment were not reported, but it seems likely this may have been due to having milder malocclusions or other similar reasons. In this situation, participants may then have different psychosocial impacts than those seeking and accepting orthodontic treatment, all of which can introduce bias.

- **Different types and severity of malocclusion:**

The majority of the studies did not report the types of malocclusions which were included. Only three studies reported malocclusion type (Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) and, as such, limited comparisons between studies were possible.

Burden and Pine (1995) reported that the main reason patients seek orthodontic treatment was to reduce psychosocial problems related to dental and facial appearance. Many factors related to malocclusion might have a social impact, such as anterior tooth alignment, tooth shape and position, profile and overjet. However, this impact may also vary between patients (Agou *et al.*, 2011). It has been reported that adolescent patients with Class II malocclusions have a higher risk of negative self-esteem than Class I and Class III malocclusions (Sun and Jiang, 2004). Shaw *et al.* (1980a) also noted that anterior crowding had more effect on psychological well-being in children than a large overjet. It is not possible to assess the impact of such factors when a study does not state the types of malocclusions included.

Severity of malocclusion may also have an effect; participants with more severe malocclusions have been reported as having greater impacts on QoL (Masood *et al.*, 2013). In this review, Dann *et al.* (1995) included patients with an overjet $\geq 4.5\text{mm}$, but the amount of reduction as a result of early treatment was specified as a mean value of 2mm, which is a relatively small change. Additionally, their study included one phase of orthodontic treatment for Class II patients and their goal was growth modification without any attempt to correct anterior tooth position. All of these

factors may have resulted in relatively limited clinical change and this may limit the extent of psychosocial change which could be anticipated.

Likewise, Albino *et al.* (1994) specified in their study that patients were included if they had mild to moderate malocclusions and, therefore, some of these patients may have experienced only relatively small psychosocial changes as a result of orthodontic treatment. In contrast, some other studies did not actually comment on the severity of malocclusions included. It is clearly important to specify types and severity of malocclusion to enable readers to know those which may affect psychosocial outcomes to a greater extent and reporting of similar clinical trials in the future should include this.

- **Different types of orthodontic treatment:**

As a result of the different types of malocclusions included in the studies, there were also different types of orthodontic interventions carried out. Treatments included functional and other orthopaedic-type appliances, headgear, removable and fixed appliances. This means that the treatment aims and results may also vary; for example, O'Brien *et al.* (2003) stated that the aim was to reduce the overjet in their Class II division 1 treatment group using the Clark Twin-block appliance and Dann *et al.* (1995) specified that they did not seek to correct the position of the anterior teeth in their study of Class II patients. Clearly this may affect the end of treatment occlusion and this, in turn, may affect any resultant psychosocial effects. Albino *et al.* (1994) reported the use of removable appliances, fixed appliances, headgear or lip bumper or rapid maxillary expansion. These treatment techniques suggest that the patients included in the study had different types of malocclusions which may not all affect psychosocial outcomes to the same extent. Additionally, not all malocclusions have aesthetic implications associated with them.

Four studies reported the use of removable and/or fixed appliances (Birkeland *et al.*, 2000; Schmidt *et al.*, 2008; Jung, 2010; Feu *et al.*, 2013). The study by Jung (2010) found that fixed appliance orthodontic treatment affected self-esteem in adolescent girls, although there was no statistically significant difference after treatment with removable appliances. This could potentially have been because the malocclusions were less severe or the malocclusions may not have been completely corrected using the removable appliances.

It is clear that it is important to clarify the type of orthodontic treatment included in studies and to establish which type of treatment may affect psychosocial aspects, in order to allow comparisons between studies.

- **Loss to follow-up:**

The causes and the extent of loss to follow-up in clinical research are important to consider. The high percentage loss to follow-up in some of the studies raises the likelihood of attrition bias and this may affect the conclusions which can be drawn based on the results of the studies.

Loss to follow-up can produce bias, however, an intention-to-treat analysis (ITT) can be used to reduce the risk of this affecting the conclusions. It is then possible to include all patients, regardless of withdrawal from treatment or deviation from the protocol (Fisher *et al.*, 1990). Two RCTs reported the use of an ITT analysis in order to determine whether there was any significant bias associated with loss of patients to follow-up (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012).

In the O'Brien *et al.* (2003; 2009) study, 25 patients were lost to follow-up from the treatment group at T2 and 19 from the control group. Of the 25 treatment group patients, 13 accepted their occlusion. The authors reported the use of an intention-to-treat analysis at T2 and included these 13 patients to reduce the bias that might be associated with their loss from the study. Mandall *et al.* (2010; 2012) reported that 10 participants were lost to follow-up at T3; 5 participants from each of the treatment and control groups. The authors reported that there was no statistically significant attrition bias due to this loss to follow-up when the baseline characteristics of the patients remaining in the study were compared with those who were lost to follow-up.

It would appear that there may have been systematic loss to follow-up in some studies, where control/untreated participants sought orthodontic treatment somewhere else due to delayed treatment (Albino *et al.*, 1994; Agou *et al.*, 2011; Feu *et al.*, 2013). Albino *et al.* (1994) described loss to follow-up of five participants from the treatment group and 12 from the control group. In the Feu *et al.* (2013) study, the total loss to follow-up was 34 of the 318 patients recruited; 5 of 92 participants from the treatment group, 23 of 124 participants from the waiting list group and 6 of 102 participants from the school group. Thus, the largest loss was

from the waiting list group; the authors noted that 17 participants reached the top of the waiting list and started orthodontic treatment during the study and were then technically lost to follow-up. Similarly, in the Agou *et al.* (2011) study, there was a higher loss to follow-up from the control group, with 24 participants lost to follow-up from the treatment group at T2 and 57 from the control/untreated group. This potential systematic loss to follow-up might introduce bias and this in turn could affect conclusions drawn.

In the Dann *et al.* (1995) study, there were 17 participants who were lost to follow-up but it was not clear whether they belonged to the treatment or control groups. The authors also reported that two participants were excluded due to highly inconsistent questionnaire responses; removing inconsistent data in this way may introduce bias in itself. The authors did not perform an intention-to-treat analysis to account for loss to follow-up.

Four studies were unclear in their reporting of the loss to follow-up so it is difficult to ascertain whether the loss was systematic or random and determine how it could have affected the outcomes drawn (Korabik, 1994; Dann *et al.*, 1995; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Arrow *et al.*, 2011).

The two studies with the longest follow-up periods, the Cardiff study (Kenealy *et al.*, 2007; Shaw *et al.*, 2007) and the Arrow *et al.* (2011) study were longitudinal studies with 20 year and 17 year follow-up, respectively. These studies showed a high loss to follow-up and, as a consequence, there is a high risk of bias in both studies. Furthermore, these studies did not report the types of malocclusions included and there was little psychosocial data collected at baseline (T1) to allow comparison. The limitations of these studies are clear and result in them being classified as having a high risk of bias.

In the Cardiff Study, there was approximately 70% loss to follow-up at 20 years (Kenealy *et al.*, 2007; Shaw *et al.*, 2007). The authors stated that the participants at the end of the study retained the main characteristics as the original sample; however, the generalisability of the findings to the whole sample cannot be guaranteed. All of these issues raise the possibility of bias and concern regarding robustness of the conclusions drawn.

- **Lack of sample size calculation:**

In clinical studies, it is important to calculate a sample size. If the sample is too small to detect differences, this may lead to studies which are unethical or can produce misleading results (Type II errors). In contrast, if a sample is too large this may lead to an unnecessary increase in time, cost and efforts. To minimise the possibility of such errors, a sample size calculation should be performed as part of the study design (Patel *et al.*, 2003).

In this review, a sample size calculation was reported in only seven of the studies and only four studies used a sample size calculation based on the OHQoL or psychosocial measures (Mandall *et al.*, 1999; de Oliveira and Sheiham, 2003; 2004; Feu *et al.*, 2013; Benson *et al.*, 2015), the other calculations were based on dental measures (e.g. PAR Index) (Mandall *et al.*, 2010; 2012). This clearly affects whether the study has appropriate power for the psychosocial outcomes (McCrum-Gardner, 2010) and, if the study is underpowered, a clinically relevant effect may be overlooked (Nguyen *et al.*, 1999). Therefore, the studies that did not report the use of a sample size calculation or those which undertook a sample size calculation based on clinical outcomes rather than psychosocial measures could be underpowered and have failed to find a significant difference even if one existed.

A retrospective power calculation was performed for the O'Brien *et al.* and Mandall *et al.* studies as part of this review to establish the power when considering the psychosocial outcomes. The O'Brien *et al.* (2003; 2009) study was slightly underpowered at 75% at T2 but had adequate power at T3 (90%), while the Mandall *et al.* (2010; 2012) study appeared to be slightly underpowered to detect differences if they existed. There were, however, certain assumptions in these calculations.

The fact that we do not appear to have research evidence showing QoL or psychosocial benefits as a result of orthodontic treatment may potentially be due to lack of power in the studies reported in the literature, and this is an important consideration in this field.

- **Different ethnicity/cultural/social aspects:**

Seven studies specified the ethnicity of participants and stated that the participants were Caucasian, non-Caucasian, Asian, Hispanic, White, Black and other. One study reported that ethnicity was not an important variable regarding orthodontic

aesthetic self-perception (Mandall *et al.*, 1999). However, there might be ethnic and cultural differences regarding dental and facial appearance. In a study conducted in the USA, it was reported that one of the most frequent reasons for seeking orthodontic treatment was protrusion of the upper incisors (Dann *et al.*, 1995), while in other countries such as Korea there are fewer patients with Class II malocclusions (Jung, 2010). Consequently, an increased overjet may be a less common reason for seeking orthodontic treatment in these countries. Therefore, ethnicity should be taken into consideration when evaluating the psychosocial impacts of malocclusion and orthodontic treatment, because different malocclusions may result in different effects depending on where the study is undertaken.

The studies included in this review were predominately from the UK, USA, Canada and Brazil. Studies from other countries (in Asia and Africa) were lacking and this means that the generalisability of the results is affected. Cultural difference between countries may affect results; therefore, more studies are needed from other countries to contribute to the knowledge base.

- **Gender effects:**

Another source of heterogeneity includes the impact associated with gender. The effect of gender was investigated in only two studies; one study found that adolescent girls with maxillary anterior crowding were found to have lower self-esteem than girls with protrusion. It was also found that girls had significantly improved self esteem following fixed appliance treatment but the same was not seen for boys (Jung, 2010). The other study showed that gender differences became more evident from 11 to 15 years of age, with more girls than boys developing negative self-evaluation (Birkeland *et al.*, 2000). The effect of gender should be considered as girls could potentially show more concern about aesthetics than boys. However, the majority of the studies in this review either did not investigate gender differences or found no gender differences and this may reflect the increased tendency for both genders to have concerns regarding aesthetics.

- **Differences in the assessment tools/outcome measures used and the appropriateness of the measures:**

There were a large number of different questionnaires used in the studies included in this review. While this reflects the significant developments in OHRQoL and

psychosocial measures which have occurred (McGrath and Bedi, 1999), the large number of measures limits the comparisons which can be made. This was one of the reasons why meta-analyses proved so difficult in this review. In order to discuss the different studies further, the OHRQoL and psychosocial measures will be considered separately.

OHRQoL measures:

The studies included in this review reported the use of a number of OHRQoL outcome measures, for example: CPQ 11-14, COHRQoL, YQoL, OHIP-14 and OIDP.

In a number of studies, the CPQ11-14 questionnaire was used in conjunction with other QoL or psycho-social measures (Taylor *et al.*, 2009; Agou *et al.*, 2011; Benson *et al.*, 2015). Agou *et al.* (2011) found a statistically significant difference in total CPQ scores at T2 between the treatment and control groups, although no p-value was quoted. However, when the Psychological Well-Being score (PWB) was included as a covariate, the differences were significant for only one subscale (Emotional Well-being). The results of the study also showed that children with better PWB reported better OHRQoL regardless of any orthodontic treatment, while children with low PWB who did not receive orthodontic treatment showed poorer OHRQoL. Therefore, they concluded that children with low PWB may benefit more from orthodontic treatment than children with better PWB. There are a number of strengths and weaknesses which should be taken into account in this study. Firstly, it did control for pre-treatment psychological aspects. The CPQ 11-14, which is becoming popular in research, shows acceptable validity and reliability (Jokovic *et al.*, 2002; Marshman *et al.*, 2005; O'Brien *et al.*, 2006; Abreu *et al.*, 2013). The CPQ has also been found to be responsive to changes resulting from orthodontic treatment with a moderate effect size. However, the authors reported the need for larger sample sizes and different treatment settings to confirm this finding (Agou *et al.*, 2008). The CPQ has some limitations in orthodontic studies though; the main limitation being that it includes four subscales, two of which are related to oral symptoms and functional limitations, and orthodontic treatment may not affect these aspects or may have very limited effects. This may explain the non-significant results for these two subscales in the Agou *et al.* (2011) study.

Taylor *et al.* (2009) reported the use of the YQoL and CPQ 11-14 and concluded that orthodontic treatment did not appear to affect general QoL or OHRQoL, despite there being some evidence for improved appearance, oral function, health and social well-being. However, there was a statistically significant difference between the pre-comprehensive and post-interceptive groups ($p < 0.001$) for the oral health item of the CPQ 11-14. The participants completed a modified version of the YQoL which was originally developed to measure QoL in 11–18 year olds with acquired and congenital craniofacial conditions; this questionnaire includes several subscales, one of which assesses Facial Differences (YQoL-FD) and this is unlikely to be relevant for the majority of orthodontic patients. This questionnaire has been validated (Edwards *et al.*, 2005), but it is not clear whether the modified version has also been validated. It may also be that this questionnaire was not sensitive to changes due to orthodontic treatment as it is a questionnaire developed for more severe dentofacial problems.

Benson *et al.* (2015) conducted a study using the CPQ11-14 to evaluate the OHRQoL and the CHQ-Child Self-Report Form to measure self-esteem. The authors found that OHRQoL improved in adolescents over time, regardless of whether or not they underwent orthodontic treatment. They also suggested that individual and environmental characteristics might affect OHRQoL. However, there were no results for the different domains of the CPQ11-14 (oral symptoms, functional limitations, emotional and social well-being) and, as explained earlier, orthodontic treatment may affect some of these domains but not all.

The study by de Oliveira and Sheiham (2003; 2004) used the OHIP-14 and OIDP and found that adolescents who had completed orthodontic treatment had significantly fewer oral health impacts in daily life than untreated patients or those currently undergoing orthodontic treatment. A statistically significant difference ($p = 0.001$) was found between the three groups for the 'smiling, laughing and showing teeth without embarrassment' subscale of the OIDP. However, the other subscales related to eating, speaking, sleeping and sport did not show significant differences. Orthodontic treatment rarely leads to differences in eating, speaking, sleeping and sport, so some of the domains of the questionnaire may not be sufficiently sensitive for assessment of orthodontic outcomes. Additionally, the children answered the questionnaire by stating if they had an impact or not and yes/no categorical answers may fail to identify occasional impacts. It is also of note that this questionnaire was originally developed for adults; another version has been developed for children

(Child-OIDP), but it was published after these studies so was not utilised (Gherunpong *et al.*, 2004). One of the positive aspects of this cross-sectional study was that it was one of the few studies, which utilised a sample size calculation based on the psychosocial outcome measure rather than clinical measures. However, being a cross-sectional study, there was high risk of bias and this must be borne in mind when interpreting the results.

Importantly, in the Kenealy *et al.* and Shaw *et al.* (2007) studies, no significant quality of life changes were found in adults who received orthodontic treatment in comparison with non-treated adults. However, the questionnaires that were used related to general health and QoL rather than OHRQoL and may not be sufficiently sensitive to changes associated with orthodontic treatment.

Based on the findings from these studies, there is limited evidence regarding changes in OHRQoL due to orthodontic treatment. The OHRQoL tools used were largely generic though and were not developed specifically for malocclusion and orthodontic treatment. Furthermore, some of the scales, such as the Oral Health Impact Profile (OHIP), were not developed for use with children or adolescents and this may affect the validity and reliability of the instrument and the possibility of patients finding some items irrelevant (Cunningham and O'Brien, 2007).

A questionnaire has recently been developed to measure OHRQoL in orthodontic patients aged 10 to 16 years; this was based on in-depth semi-structured interviews and identified the reasons why participants seek orthodontic treatment (Benson *et al.*, 2016; Patel *et al.*, 2016). Collaboration between the UCL Eastman Dental Institute and the University of Sheffield developed and tested this questionnaire. It is important that studies focus on developing an internationally agreed valid age-specific OHRQoL instrument for use in orthodontic treatment, to be used in this area of research. This ensures that OHRQoL impacts associated with orthodontic treatment can be fully investigated in the future using appropriate questionnaires.

Psychosocial measures:

A range of psycho-social measures were identified in this systematic review, but mainly included assessments of self-esteem and self-concept. Generally, research has linked high self-concept to many positive outcomes, such as healthy social relationships and positive perceptions by peers. In contrast, low self-concept has

been linked to negative outcomes, such as health problems and antisocial behaviour (Trzesniewski *et al.*, 2003). Similarly, it has been proposed that there is a relationship between malocclusion and low self-concept (Perillo *et al.*, 2014). Individuals with low self-concept may avoid smiling in order to hide their teeth, they may also be teased because of the appearance of their teeth and believe that orthodontic treatment will improve self-concept and success in life (Badran, 2010). Therefore, much emphasis has been placed on orthodontic treatment improving self-concept and self-esteem.

The studies included in this review reported the uses of a number psychosocial outcome measures, for example: the Piers-Harris Self-Concept Scale, Rosenberg Self-Esteem Scale and the Oral Aesthetic Subjective Impact Scale (OASIS). The majority of psychosocial instruments were not originally designed to be used with orthodontic patients and many of these measures were devised for use with general dental or medical patients or in community settings. This may clearly affect research outcomes because they are now being used to assess a condition for which they were not developed. Of the questionnaires identified in this systematic review, the Oral Aesthetic Subjective Impact Scale (OASIS) is the only measure developed to evaluate the degree of concern about the dentition (Mandall *et al.*, 1999). There is limited evidence of the validity of the scale, but one study reported a cross-cultural adaptation of a Brazilian version of the scale with the adopted scale showing good psychometric properties (Pimenta and Traebert, 2010).

Some of these measures were also developed many years ago which may decrease their appropriateness, for example the Piers-Harris Self-Concept Scale and the Rosenberg Self-Esteem Scale. The Piers-Harris Self-Concept Scale should be used with caution because the population norms were derived from a non-clinical population of schoolchildren in the 1960s. Some researchers have questioned the use of this questionnaire, despite its validity it has been said that might be insensitive to maturational changes (Korabik, 1994). Furthermore, it does not specifically measure self-concept related to the face, teeth and occlusion (Mandall *et al.*, 2012). None of the studies in this review which used the Piers-Harris self-concept scale found a statistically significant change in self-concept in the long term after orthodontic treatment, although some short-term improvements were found and these may be important to individual patients (O'Brien *et al.*, 2003; 2009).

Likewise, the Rosenberg Self-Esteem Scale (Rosenberg, 1965), which is one of the most widely used self-esteem measures in social science research, was originally developed in the 1960s with 5,024 high school students from 10 randomly selected schools in New York, and this may limit its generalisability in contemporary studies (Rosenberg, 1965). This scale has been used in a study of the psychological influences of malocclusion and orthodontic treatment (Johal *et al.*, 2015) and it has proven reliability for the general population and for orthodontic patients (Shaw *et al.*, 2007). However, it was designed for older adolescents and adults and it is possible that it is not appropriate in research regarding orthodontic treatment in younger children and adolescents.

Summary:

Overall, there was marked heterogeneity between the studies regarding types of malocclusion, types of orthodontic treatment, assessment tools, ethnicity/ cultural aspects and others. There was clinical, methodological and statistical heterogeneity between studies and as a result of this heterogeneity, it is difficult to make definite conclusions regarding the effects of orthodontic treatment.

Despite the failure to find evidence to support or refute QoL and/or psychosocial changes as a result of orthodontic treatment, patients appear to seek orthodontic treatment to improve their oral-health-related quality of life (Masood *et al.*, 2014). Furthermore, orthodontic treatment may produce other psychosocial impacts, for example: increased interpersonal attraction (Korabik, 1981), increased achievement or motivation (Lucker *et al.*, 1981), and less bullying related to malocclusion. However, these aspects were not studied in the papers included in the systematic review.

There is also debate as to whether there is a need to measure specific outcomes such as self-concept when assessing changes associated with orthodontic treatment, or whether using OHRQoL as a more “global” assessment can provide adequate information. This is something which should be considered in future research of this type.

2.4.2 Meta-analysis:

The Piers-Harris Self-Concept Scale was one of the most commonly used scales in the RCTs in this review, therefore, a meta-analysis was undertaken to explore its use. Two studies were involved in this analysis (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) and two studies were excluded for the reasons explained in the review (Korabik, 1994; Dann *et al.*, 1995). The result of this meta-analysis showed a statistically significant difference in self-concept between the patient and control groups after the first phase of early orthodontic treatment [(SMD: 0.368; 95% CI: 0.092 to 0.644)] and suggests there may be beneficial effects associated with early treatment. However, there was no statistically significant difference between the two groups later in treatment [(SMD: 0.102; 95% CI: -0.180 to 0.383)]. This suggests that neither treatment modality was significantly better than the other in terms of enhancing self-concept in the longer term, but does not allow any conclusions to be reached regarding orthodontics in its entirety (purely the difference between early and later treatment).

2.4.3 Discussion of strengths and limitations of the evidence included in this review:

This systematic review included four RCTs, which are one of the most powerful tools in clinical research (Albino *et al.*, 1994; Dann *et al.*, 1995; O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012). Two of the RCTs were conducted extremely well and the papers were clearly presented, but they were still associated with a high risk of performance bias due to the inability to blind the clinicians and the patients to their group allocation and due to lack of sample size calculations based on the psycho-social measure (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012).

A larger number of observational studies were included and these were classified according to whether they were cross-sectional or longitudinal cohort studies. Longitudinal designs are often used as the next best level of evidence after RCTs, and this is frequently a more feasible approach in orthodontic research (Agou *et al.*, 2011). Additionally, they often produce a better level of evidence than cross-sectional studies (Locker, 1998). It has been reported that systematic reviews of observational studies always have inherent problems (Stroup *et al.*, 2000), including selection bias and the presence of confounders which are not managed as well as

in RCTs. However, a well-designed observational longitudinal study can play a key role in evidence-based research (Ligthelm *et al.*, 2007).

In this review, a high risk of bias was reported for all observational studies for reasons including the methodology itself, lack of sample size calculation, loss to follow-up, incomplete data and others. One longitudinal study was associated with a very complex methodology (Korabik, 1994). The study was difficult to follow in parts and the author used what was termed a 'quasi-experimental design', presumably attempting to combine the advantages of both cross-sectional and longitudinal studies. The design of the study was difficult to follow and the small sample size means that there was likely to be reduced power in the analysis.

The follow-up period of the longitudinal studies varied between the studies. Longer periods of follow up add strength to studies (Kenealy *et al.*, 2007; Shaw *et al.*, 2007). However, high loss to follow-up is a problem in such studies (Bildt *et al.*, 2001). In the Cardiff study, approximately 70% of the participants were lost to follow-up after 20 years and approximately 85% were lost to follow up in the Arrow *et al.* (2011) study. Therefore, the results of longitudinal studies with a high loss to follow-up should be evaluated carefully. Although there are benefits to such studies; loss to follow-up is likely to introduce significant bias as the participants may not be representative of the initial study group (Bildt *et al.*, 2001).

The majority of the studies did not specify the type or the severity of the malocclusions which they included (Albino *et al.*, 1994; Korabik, 1994; Mandall *et al.*, 1999; Birkeland *et al.*, 2000; de Oliveira and Sheiham, 2003; 2004; Kenealy *et al.*, 2007; Shaw *et al.*, 2007; Schmidt *et al.*, 2008; Taylor *et al.*, 2009; Badran, 2010; Agou *et al.*, 2011; Arrow *et al.*, 2011; Feu *et al.*, 2013; Benson *et al.*, 2015). This might result in important information being overlooked because different types or severities of malocclusion might have different effects on quality of life and other outcomes. For example, Albino *et al.* (1994) specified that patients were included if they had mild to moderate malocclusions and, therefore, some of these patients may have had relatively small clinical changes as a result of orthodontic treatment, resulting in little psychosocial change.

A further limitation was regarding the questionnaires; the majority of studies used questionnaires with some evidence of validity and reliability. However, a wide range of psychosocial and QoL/OHRQoL outcome measures were used so it was

impossible to combine the studies for meta-analysis. Only one questionnaire was developed specifically for use with orthodontic participants and that was the OASIS (Mandall *et al.*, 1999).

In addition, the ability to answer questionnaires may be affected by their length and the number of questionnaires used in total. In the longitudinal Cardiff study, 14 questionnaires were used at final follow-up which might well introduce bias due to participant fatigue. Participants may not then answer questions fully or concentrate whilst answering them and there are inherent problems associated with that (Kenealy *et al.*, 2007; Shaw *et al.*, 2007).

All included studies showed some limitations, for example: lack of sample size calculation, use of questionnaires not designed for orthodontics or for that age group, use of a large number of questionnaires which may have caused fatigue, and individual patient variation which might have an effect in small cohorts.

A number of important issues should be considered for future studies:

1. Calculation of sample sizes based on QoL or psychosocial outcomes as well as on clinical outcomes.
2. The use of contemporary questionnaires designed for research in orthodontics and for the age group in question.
3. Including an acceptable number of questionnaires to reduce participant fatigue.

2.4.4 Discussion of strength and limitations of the systematic review:

One of the strengths of this systematic review is that the Cochrane recommendations were followed and a number of steps were taken to minimise bias within the review, including having a detailed protocol which was developed before commencing the study. The wide literature search included the grey literature and studies in English and in other foreign languages. A number of different databases were used, with search strategies developed to include all possible search terms and ensure that the QoL and psycho-social impacts of orthodontic treatment were fully investigated.

The protocol underwent many iterations before the final version was approved. Different factors, such as age and gender, may affect the outcomes of orthodontic

treatment. Therefore, in order to reduce the possibility of bias by the inclusion of too many variables, the age of participants included in this review was specified as 7 to 16 years old at the time of commencing treatment. This ensured the focus was on children and adolescents rather than adults, but also took into account the fact that in some countries patients commence treatment at an earlier stage than others.

Kappa scores were calculated to measure the agreement between the researchers during the abstract and full-text selection stage. There was good agreement in the initial search and moderate agreement in the updated search. The reason behind the better agreement for the initial search is probably due to there being more papers included in the initial search, so any disagreement between the two researchers would impact less on the kappa scores.

The main limitation of this review was that some studies had to be excluded because the authors did not reply to our queries and there may have been some useful data which was not included (Table 11). Furthermore, in the meta-analysis, only two RCTs were included (O'Brien *et al.*, 2003; 2009; Mandall *et al.*, 2010; 2012) and the patients had different types of malocclusions and orthodontic treatment. Also, assumptions had to be made for the calculation of SDs for the O'Brien *et al.* (2003) study.

2.4.5 Comparison with other systematic or narrative reviews:

Recently, a number of systematic reviews have investigated the impact of malocclusion and/or orthodontic treatment on QoL and OHRQoL. Some of these studies assessed the effects of malocclusion rather than orthodontic treatment. Furthermore, they have often evaluated only QoL and OHRQoL rather than including wider psychosocial measures also. Therefore, this systematic review searched both the psychosocial and OHRQoL literature in children and adolescent patients. The study was restricted to children and adolescents because the effects might differ from those in other age groups.

Two systematic reviews examined the effects of malocclusion on QoL. Dimberg *et al.* (2015) assessed the evidence regarding malocclusion and its impact on QoL among children and adolescents. They concluded that malocclusion has negative effects on OHRQoL, especially in the social and emotional dimensions. Similarly, Liu *et al.*

(2009) conducted a systematic review to evaluate evidence of the relationship between malocclusion/orthodontic treatment need and QoL. The authors included children, adolescents and adults and they concluded a moderate relationship between malocclusion/orthodontic treatment need and negative impacts on HRQoL.

A further two systematic reviews investigated the impact of malocclusion and/or orthodontic treatment on QoL. Zhou *et al.* (2014a) assessed evidence of the relationship between orthodontic treatment and QoL but included adults as well as adolescents in their review. They found that orthodontic treatment is associated with moderately improved OHRQoL in adolescent and adult patients. They reported that the Child Perception Questionnaire (CPQ) and the Oral Health Impact Profile (OHIP) were the most frequently used measures, but noted that different assessment methods in the studies limited the ability to do meta-analyses. Andiappan *et al.* (2015) also conducted a systematic review and meta-analysis to study the impact of malocclusion and its treatment on OHRQoL in adults. The authors limited their review to those studies using the OHIP-14 and showed that scores were significantly lower in individuals without malocclusion and in individuals after orthodontic treatment, thus indicating better OHRQoL. Importantly, comparisons of the results and conclusions of these reviews and meta-analyses with the current review should be made with caution due to inclusion of adults and orthognathic studies in the other reviews and this might result in different OHRQoL impacts compared with conventional orthodontic treatment in younger patients only.

2.5 Conclusions:

This systematic review studied the QoL and psychosocial impacts of orthodontic treatment in adolescent patients. However, the limitations of the evidence in the review means that there cannot be a definite conclusion and there was inadequate evidence to support or refute the hypothesis that there are psychosocial and QoL benefits associated with orthodontic treatment in children and adolescents.

- There were few statistically significant psychosocial/ QoL changes in association with orthodontic treatment. It is, however, important to stress that only four of the 17 studies undertook a sample size calculation based on the psychosocial outcome being assessed. None of these four studies were RCTs, two were cross-sectional and two were longitudinal studies.
- There was significant heterogeneity in the studies. Most heterogeneity could be accounted for by variations in sample characteristics and outcome measures. The lack of a universal outcome measure in reporting impacts of orthodontic treatment is an important issue, and efforts must be made to develop universally accepted outcome measures for orthodontic patients.
- The meta-analysis revealed that there was a statistically significant difference between the early treatment and control groups in the short term (SMD: 0.368), but not in the long term (SMD: 0.102). Therefore, there appear to be benefits associated with early treatment in the initial stages but whether they remain in the longer term is debatable.

2.6 The relationship between the systematic review and Chapters III and IV

The systematic review showed that it was not possible to support or refute the evidence regarding the psycho-social/ QoL impacts of orthodontic treatment in adolescent patients based on the existing evidence. This highlighted the need to study this area further and, in particular, to study the social impacts of malocclusion and orthodontic treatment.

Chapter III was a longitudinal controlled questionnaire based study in which efforts were made to overcome some of the limitations highlighted in those studies included in the systematic review. This was feasible for some of the limitations, but not all, and this will be discussed later in the discussion of Chapter III.

The search for appropriate questionnaires to use in Chapter III also highlighted the limitations of quantitative research, especially questionnaire based research. As a result of this, Chapter IV was a qualitative study designed to explore the social impacts of malocclusion in adolescent patients utilizing methodology which has been noted to be useful for studies investigating other subjective aspects.

Chapter III: The social impact of malocclusion and functional appliance treatment for Class II division 1 malocclusion in adolescent patients

3.1 Introduction

A number of studies have examined the different social impacts of malocclusion and orthodontic treatment in adolescents and some studies have linked certain types of malocclusion with specific social impacts (O'Brien *et al.*, 2003; 2009; de Oliveira and Sheiham, 2004; Mandall *et al.*, 2010; 2012; Seehra *et al.*, 2011a; Johal *et al.*, 2015). The systematic review in Chapter II showed variation between studies regarding the impact of orthodontic treatment and this remains a subject of some controversy.

3.2 Subjects and methods

3.2.1 Aims of the study

To look at the social impacts in a group of adolescent orthodontic patients before and after removable functional appliance treatment for Class II Division 1 malocclusions and to compare the findings with a control group of orthodontic patients of the same age range who were not undergoing any treatment.

A decision was made to look specifically at social impacts rather than broader psycho-social and QoL impacts. In recent years, a number of researchers working in this field of research have suggested that the focus of research should be on *social* impacts rather than the wider *psycho-social* impacts.

3.2.2 Research questions

The focused questions for this longitudinal clinical study were as follows:

I. Principal research question

Does orthodontic treatment being undertaken for the treatment of prominent upper front teeth (Class II Division 1 malocclusion) have social benefits?

IV. Secondary research question

Do patients with Class II division 1 malocclusions have greater social impacts than seen in a control group of patients with a range of different malocclusions?

3.2.3 Null Hypothesis

In Class II Division 1 patients who are undergoing removable functional appliance treatment there are no substantial social benefits as a result of orthodontic treatment.

3.2.4 Study design

Treatment outcomes in a study of this type would ideally be assessed using randomised controlled trial (RCT), however, this is difficult in orthodontics for ethical reasons. It has been suggested that prospective longitudinal trials might be a feasible alternative, therefore, a prospective controlled longitudinal questionnaire based study was planned to evaluate the social impacts of malocclusion and removable functional appliance treatment among adolescent patients.

3.2.5 Ethical Considerations

Study approval

Research and Development approval was granted by University College Hospitals Foundation Trust London and a favourable ethical opinion was obtained on the 28th October 2013 (REC reference 13/LO/1256) from Chelsea Research Ethics Committee (Appendix 5).

3.2.6 Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for the treatment and control groups were as follows (Tables 33 and 34).

The treatment group	
Inclusion criteria	Exclusion criteria
10 to 14 years old (inclusive)	Patients with craniofacial syndromes
Male or female	Individuals with traumatic or pathological facial conditions
Class II Division 1 malocclusion	Patients with diagnosed behavioural or psychological disorders as detailed on the medical history.
Overjet \geq 6mm	
About to commence functional appliance treatment	
Patient willing to participate in the study	
Parent or legal guardian agrees to provide consent and patient agrees to assent	

Table 33: Inclusion/exclusion criteria for participants in the treatment group

The control group	
Inclusion criteria	Exclusion criteria
10 to 14 years old (inclusive)	Patients with craniofacial syndromes
Male or female	Individuals with traumatic or pathological facial conditions
Any type of malocclusion, but not ready to start orthodontic treatment for at least 6-12 months	Patients with diagnosed behavioural or psychological disorders as detailed on the medical history
Patient willing to participate in the study	
Parent or legal guardian agrees to provide consent and patient agrees to assent	

Table 34: Inclusion/exclusion criteria for participants in the control group

3.2.7 Recruitment of participants

Patients were recruited by a single researcher (HMA) from the Orthodontic Department at the Eastman Dental Hospital, UCLH Foundation Trust. Recruitment started on the 18.11.2013 and the final questionnaire was completed on the 16.11.2015.

Treatment group: Participants were recruited from the postgraduate orthodontic clinic during the appointment when records were taken. Patients with Class II division 1 malocclusions who were about to start removable functional appliance treatment and who met the inclusion and exclusion criteria were invited to participate (Table 33).

Control group: Participants were recruited from new patient clinics. Patients with any type of malocclusion were invited to participate, provided they were not ready to commence orthodontic treatment for at least 6 to 12 months and met the inclusion and exclusion criteria (Table 34). This control group is not a perfect control group, but allowed for potential maturational effects to be controlled for. Due to ethical issues it would not have been possible to delay treatment unnecessarily. Consideration was given to the recruitment of the control group through other means (e.g. school cohorts) but all approaches have some limitations.

3.2.8 Consent process and Confidentiality

Patients in the treatment group were initially asked by the clinician treating them if they were interested in participating. If they showed interest in being involved in the study, the researcher (HMA) then explained the details to the prospective participants and their parent/guardian and gave the relevant PILs (patient and parent information leaflets) (Appendices 6 and 7). Patients and parents were then allowed as much time as they needed to consider if they would like to be involved in the study, this was usually until their next visit but had to be prior to the functional appliance being fitted. If they agreed to participate, the patient signed an assent form and the parent signed a consent form and 2 copies of the original forms were made, the original was retained in the hospital records, a copy was given to the patient and a copy was placed in the study file (Appendix 6). A refusal to participate

was accepted without any prejudice being attached to those who chose not to participate and it was stressed that their treatment would not be affected.

A similar process was followed for recruiting and obtaining consent from the patients in the control group. However, minor changes were made to the wording of the information leaflets and the assent/consent forms to explain that the patients were being invited to participate because they were not yet ready to commence orthodontic treatment (Appendix 7).

It was initially intended that respondents would be allowed to complete the questionnaire either in the department or at home. However, the Ethics Committee specified that patients had to be encouraged to complete it in the department in case they became distressed by any of the questions being asked. This was problematic for the control group as most of the patients only attended for one appointment so could not be allowed until the next review appointment to make a decision whether or not to participate, as this could have been 6-12 months away. Therefore, it was agreed by the Ethics Committee and the Research and Development Department that a letter could be sent with all new patient clinic appointments explaining about the study so that patients could then be consented on the day of the appointment if they satisfied the inclusion criteria (Appendix 8).

An electronic folder was developed to monitor recruitment, data management and analysis of data. This list of patients detailed those who commenced treatment, those lost to follow-up and those who completed the study. Reasons for patients not wishing to be included in the study and reasons for loss to follow-up were also recorded. No names were used on the questionnaires, only a unique ID and only the researchers involved in the study had access to the code for the ID numbers.

3.2.9 Development of the questionnaire

The research team liaised closely with experts in the UK and the USA regarding the most appropriate questionnaires to be used in the questionnaire in order to explore social impacts of malocclusion and orthodontic treatment in this particular age group. The separate elements of the questionnaires were collected into a booklet, which was designed to be easy to read and complete for 10 to 14 year olds. It was

then piloted on family/friends of the research team who were in this age range and completion took approximately 15 minutes.

It was intended to select questionnaires which measured the social aspects of psycho-social functioning. There is an on-going debate as to whether generic or condition specific measures should be utilised in studies of this type (Guyatt *et al.*, 1993) and, following discussion with other experts in this field (Newton, 2013) it was decided to use elements of both in this study.

The social domain of the MSCS was selected initially as it is a questionnaire which has been widely used, has a specific social sub-scale, has been psychometrically tested and it has been used successfully in orthodontic research previously (Phillips and Beal, 2009). Additionally experts who have researched in this area before recommended the use of this sub-scale (Newton, 2013; Williamson, 2013). The SAS-A was selected based on its properties, the potential importance of social anxiety in orthodontics (Ryan *et al.*, 2016) and the fact that it had been successfully used in a previous study within the department (Read, 2013).

A condition specific questionnaire was more difficult to select as there were very few questionnaires available at that time point which had been developed specifically for malocclusion and orthodontics. A decision was made to use OASIS, whilst acknowledging that there has been limited psychometric testing of this questionnaire. It was felt that OASIS provided more condition specific appearance related questions, which would test some of the issues patients were potentially concerned about (smiling etc.).

All elements of the questionnaires had some evidence of psychometric testing, with the MSCS and the SAS-A having been more extensively tested than OASIS (Braken, 1992; La Greca, 1999; Mandall *et al.*, 1999; Kerosuo *et al.*, 2004). Validity and test-retest reliability are two essential qualities of any questionnaire; validity is the extent to which the questionnaire measures what it says it is measuring and test-retest reliability is the extent to which any measure yields the same results at repeated time points (Kimberlin and Winterstein, 2008).

- **Index of Orthodontic Treatment Need-Aesthetic Component (IOTN-AC)**

The IOTN-AC was included as a subjective measure of how patients felt about their own teeth and also because it was included by Mandall *et al.* (1999) as part of the OASIS questionnaire (see later details in the section). The IOTN-AC was originally developed as a standardised rating scale to assess dental aesthetics (Evans and Shaw, 1987), but has more recently been used as a tool to determine orthodontic treatment priority, to help subjects to develop a realistic impression of their dental attractiveness and to create reproducible measures in clinical and research studies. The IOTN-AC comprises a set of 10 photographs, which are graded from 1 (the most aesthetically pleasing) to 10 (the least aesthetically pleasing). Patients were asked to select the photograph that they thought most closely represented their own dental aesthetics.

The validity of the IOTN has been questioned due to the lack of concordance between IOTN and professional opinion regarding orthodontic treatment need (Jenny and Cons, 1996b). However, in the development of the IOTN-AC, Brook and Shaw (1989) found good inter-examiner and intra-examiner reproducibility for the IOTN-AC. Beglin *et al.* (2001) compared the validity and reliability of the IOTN with the Dental Aesthetic Index (DAI) and the Handicapping Labiolingual Deviation (HLD) and found that IOTN was the most accurate index (98%) in comparison with DAI (95%) and HLD (94%). Similarly, Kerosuo *et al.* (2004) assessed the self-perception of 139 Arab students, aged 14-18 years old and found 77% agreement with the IOTN-AC, thus suggesting that the IOTN-AC can be used to reflect patient self-perceived need for treatment.

The remaining three questionnaires in the booklet were included specifically to measure social impacts:

- **The Oral Aesthetic Subjective Impact Scale (OASIS)**

This questionnaire was developed to assess subjective oral aesthetic impact in adolescent orthodontic patients (Mandall *et al.*, 1999) and was designed to evaluate the effects of malocclusion, as well as the demand for orthodontic treatment. It is a short scale consisting of five questions which measure the respondent's concern regarding their teeth and all responses are on a seven-point Likert scale. The questions ask about dental appearance, whether respondents experience nice or unpleasant comments about their teeth, if they are being teased and if they avoid

smiling or cover their mouth because of their dental aesthetics.

There is only limited data regarding the validity and reliability of the OASIS, although a number of orthodontic studies have used the scale (Claudino and Traebert, 2013; Ghijselings *et al.*, 2014). One study assessed the internal consistency of OASIS and reported good reliability with a Cronbach's alpha of 0.76 (Mandall *et al.*, 1999). As explained earlier, it was decided to use this scale because it is one of the few specifically designed for use in orthodontics.

- **Multidimensional Self-Concept Scale (MSCS)-Social subscale**

The Multidimensional Self-Concept Scale (MSCS) is a standardised instrument and was designed for use with individuals from 9-19 years of age. It assesses a child's or adolescent's adjustment in six self-concept domains: Social, Competence, Affect, Academic, Family and Physical (Braken, 1992). Each domain includes 25 items, which are scored from 1 (strongly agree) to 4 (strongly disagree). Negatively worded items are reverse scored and a higher score indicates a more positive self-concept.

In this study only the social sub-scale from the MSCS was used and this focuses on social contexts and interactions with family members, neighbours, friends and teachers which might influence an individual's social self-concept (Polloni *et al.*, 2015). The decision to use the social sub-scale separately was based on advice from psychology and social science researchers in this field at the University of the West of England (Williamson, 2013), Kings College London (Newton, 2013) and the Royal Free Hospital, London (Clarke, 2012), all of whom indicated that using a sub-scale was acceptable as long as the sub-scale was used intact. It was felt to be better to use this approach than creating a large respondent burden by using the whole scale where the majority of items were irrelevant to the study question. This scale has been used previously as a single sub-scale and found to be valid and reproducible (Williamson, 2013).

It has been reported that each sub-scale shows high reliability (Alpha Coefficient >0.90) and the total scale reliability was over 0.97 for a sample of 2,501 students (Braken, 1992).

- **Social Anxiety Scale for Adolescents (SAS-A)**

The Social Anxiety Scale for Adolescents (SAS-A) is a self-report measure designed to assess social anxiety (La Greca and Lopez, 1998). It has been used most widely with participants who are 13-17 years old, although has also been used with younger patients. The scale has 22 items (including 4 filler items) which assess 3 aspects of social anxiety: Fear of Negative Evaluation (FNE=8 items), Social Avoidance and Distress around New Peers or in New Situations (SAD-NEW=6 items), and Generalized Social Avoidance and Distress (SAD-General= 4 items). It takes around 5 minutes to complete. Prior to use in this PhD, it had been used successfully in a cross sectional study of social anxiety in the Orthodontic Department at the UCL Eastman Dental Institute (Read, 2013).

This scale showed good validity and reliability in previous studies (Inderbitzen-Nolan and Walters, 2000; Storch *et al.*, 2004; Ranta *et al.*, 2012). Ranta *et al.* (2012) examined the concurrent and discriminant validity of the SAS-A scale in 563 Finnish adolescents, aged 13-16 years old, relative to the Social Phobia Inventory (SPIN) and the Beck Depression Inventory (BDI). The authors found that the correlation between SAS-A (total) and the SPIN was high (0.67; $p < 0.01$), which suggests that the SAS-A (total) has acceptable concurrent validity. However, the SAS-A (total) was less well related to the BDI (0.34; $p < 0.01$) but was comparable with the correlation between the SPIN and BDI (0.33; $p < 0.01$). The correlations for SAS-A (total) and BDI compared with the SPIN and BDI were similar, which indicates some support for the discriminant validity of the SAS-A. Furthermore, the subscales were found to be highly correlated (0.75-0.90) with the total SAS-A score. Similar findings were reported by La Greca and Lopez (1998).

The test-retest reliability of the scale was examined by Gracia-Lopez *et al.* (2001) in a study where 175 of the 303 subjects completed the scale a second time after an average of 10 days (range 7 to 14 days) and the researchers found a relatively high correlation ($r = 0.86$). La Greca (1999) also showed that the scale had good internal consistency (Cronbach's alpha = 0.66 to 0.91).

3.2.10 Distribution of the questionnaires

All patients involved in the study completed an identical questionnaire twice; they completed the questionnaire unassisted by parents or researchers:

- **Treatment group:** Patients completed the questionnaire at the start of treatment before provision of the removable functional appliance (T1) and at the end of treatment (T2), when the overjet was considered sufficiently reduced to progress to the next stage of treatment.
- **Control group:** Patients completed questionnaires at the start of the observation period (T1) and when they returned to the department for their next review appointment 6 to 12 months later (T2).

3.2.11 Questionnaire Scoring

Questionnaires were scored according to the criteria described by the researchers who developed them, with the exception of OASIS. For the OASIS scale, the authors proposed that the questionnaire score and the child's perceived IOTN-AC score were summed to give the overall perceived oral aesthetic impact score and this provided the OASIS score. However, at the data analysis stage the statistician for this study (Dr. Aviva Petrie) felt that this was not appropriate for several reasons. Firstly, the questionnaire score is a continuous scale whilst the IOTN-AC is categorical scale (ordinal). Additionally, the scales did not have the same scale range. OASIS scores ranged from 7 to 35, while IOTN-AC scored from 1 to 10, which makes summation of the two scores inappropriate. The OASIS score was therefore calculated purely from the questionnaire, excluding the IOTN measure. However, the IOTN-AC was included in the regression analysis as a potential confounding factor. For the analysis, IOTN-AC was recoded into a binary variable according to whether the IOTN was category 1 to 5 or category 6 to 10, accepting that by doing this, some information is lost in the analysis. These categories were chosen due to the NHS acceptance criteria for treatment in the UK of a DHC of 3 and IOTN-AC of 6 for borderline cases (Department of Health, 2006).

The Multidimensional Self-Concept Scale (MSCS) scores can be presented as raw scores or as standardised scores (Table 58) to allow comparison with other studies. Both approaches were used in the analysis of the data and the conversion to

standardised scores was undertaken using Appendix 2 in the MSCS manual. Different score ranges for the whole scale are described in the manual, ranging from extremely negative self-concept to extremely positive self-concept (Table 35) (Braken, 1992).

Score range	Classification
Above 135	Extremely positive self-concept
126-135	Very positive self-concept
116-125	Moderately positive self-concept
86-115	Average self-concept
76-85	Moderately negative self-concept
66-75	Very negative self-concept
Below 66	Extremely negative self-concept

Table 35: Self-concept classifications according to standardised score ranges

The social anxiety scale was scored according to the author's instructions and the level of social anxiety classified according to the following (Table 36) (La Greca, 1998).

Score range	Classification
Total SAS-A > 50	High level of social anxiety
Total SAS-A 36 to 50	Normal level of social anxiety
Total SAS-A < 36	Low social level of anxiety

Table 36: Social anxiety classifications corresponding to standard score ranges

If participants failed to complete one or two items, the mean of the remaining individual item scores was used to estimate the value. However, if more than two items scores were missing, that element of the questionnaire was excluded from analysis. This decision was based on advice from experts in this field of research (Newton, 2013). All scoring of questionnaires and data entry was undertaken by the researcher (HMA) and a random sample of 20% of the questionnaires for both groups was also cross-checked by the primary supervisor (SJC).

Each questionnaire had a different scoring range and direction of the scoring and this was taken into consideration during statistical analysis (Table 37).

Questionnaire	Scored range	Direction of scoring
The Oral Aesthetic Subjective Impact	Minimum = 5 Maximum = 35	The higher the score, the more concern
Index of Orthodontic Treatment Need - Aesthetic Component	-----	The higher the score, the poorer the aesthetics
The Multidimensional Self-Concept Scale	Minimum =25 Maximum =100	The higher the score, the more positive the self-concept
Social Anxiety Scale for Adolescents	Minimum = 22 Maximum = 110	The higher the score, the greater the social anxiety

Table 37: Score range and direction of scoring for the individual elements of the questionnaires

Data Entry

A SPSS spreadsheet was used to include the participants' details. It was updated each time a new patient was recruited to the study and at the end of the study after the final questionnaires were scored.

The spreadsheet included the following variables:

- Patient ID
- Gender
- Age
- Group (Treatment or Control)
- Scores for each component of the questionnaire obtained at T1 and T2

3.2.12 Sample size calculation and Statistical analyses

Sample size calculation

There are no previous studies in orthodontic research which have used the combination of questionnaires selected and it was, therefore, not possible to undertake a sample size calculation at the outset. Instead, data from the first 13 patients from the treatment group and the first 10 patients from the control group to complete both questionnaires was used as an internal pilot for this purpose. The numbers were based on the number of participants who had data for both time points at the stage that the calculation was undertaken. The standard deviation (SD) was calculated for each group and the mean SD was used, alongside the clinically relevant differences, as detailed in Table 38. This process was undertaken for each of the individual questionnaires and the largest sample size was utilised. The data from the patients utilised in this sample size calculation was still included in the final analysis.

Based on an 80% power and a significance level of $p < 0.05$, it was determined that a total of 64 patients were required for the Oral Aesthetic Subjective Impact (OASIS), 56 patients for the Multidimensional Self-Concept Scale (MSCS) and 58 patients for the Social Anxiety Scale (SAS-A). Therefore, 64 patients were needed in total. In order to allow for loss to follow-up in clinical studies, it was decided that 40% (26 patients) over the estimated sample would be recruited. This showed that at least 90 patients were needed; 45 patients in each group.

	Clinically relevant difference	Treatment group		Control group		Estimated SD	Total patients needed
		N	SD	N	SD		
The Oral Aesthetic Subjective Impact (Minimum score 5, maximum score 35)	5	13	8.57	10	5.78	7.0	64
The Multidimensional Self-Concept Scale (Minimum score 25, maximum score 100)	8	13	8.14	10	11.63	10.0	56
Social Anxiety Scale for Adolescents (Minimum score 22, maximum score 110)	8	13	8.03	10	12.75	10.5	58

Table 38: Sample size calculation for the questionnaires included in the study

Statistical analyses

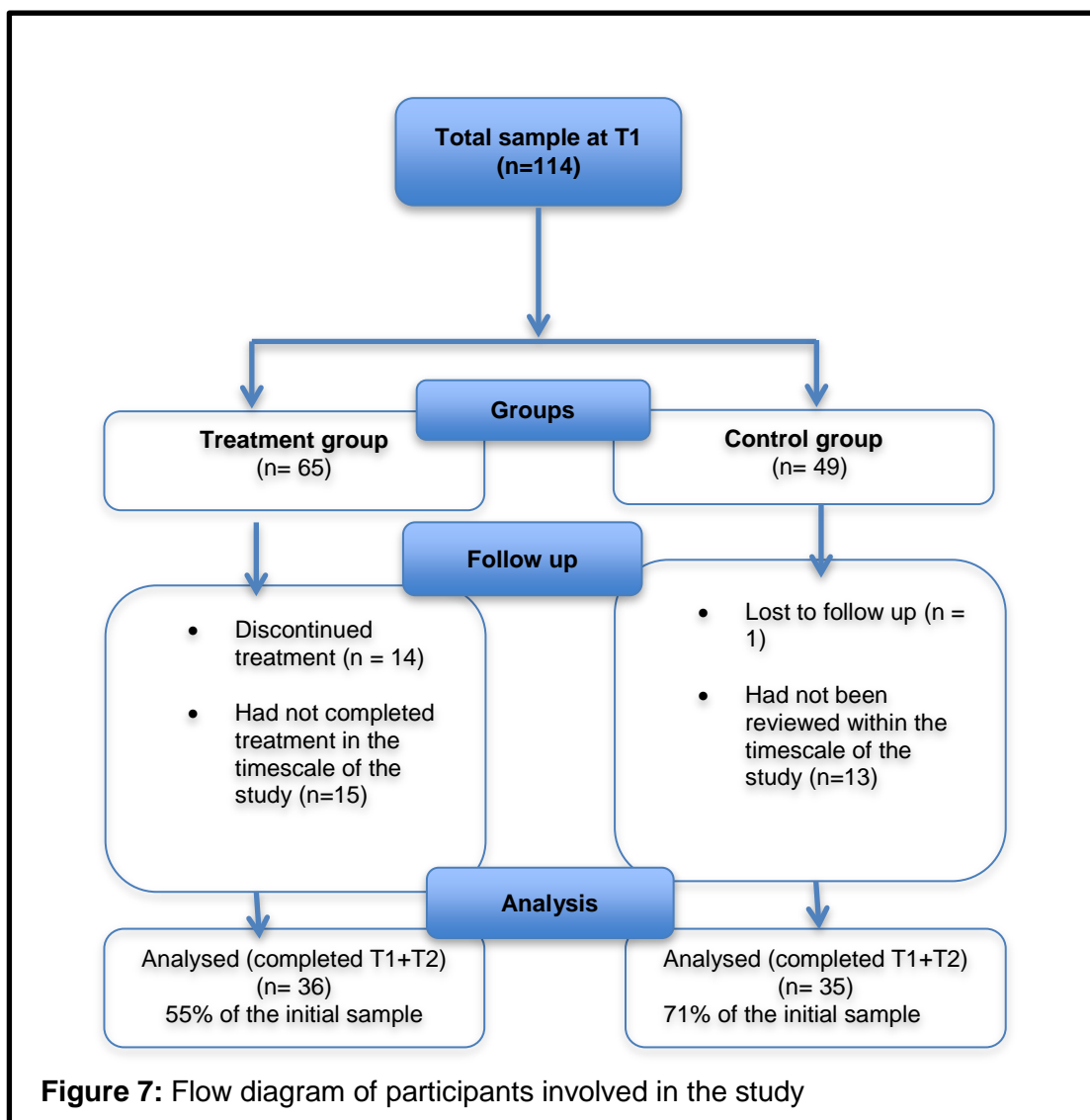
Statistical analysis was undertaken using SPSS version 22 (SPSS UK Ltd, Guildford Surrey, UK). Data was entered and analysed using descriptive and analytical statistical methods. Data was checked for normality and non-parametric analyses were undertaken where there was a non-normal distribution of data.

Univariable and multivariable regression analyses were used to assess the effects of independent variables (e.g. treatment or control group, age, gender, IOTN-AC) on each of the questionnaire scores. All assumptions were satisfied for the statistical tests used and the residuals were used to assess normality and constant variance for the regression analyses.

The significance level was set at 0.05 for all tests. There were a large number of statistical tests undertaken which increases the likelihood of significant results being spurious therefore this should be borne in mind when interpreting the results.

3.3 Results:

3.3.1. Study Progress



In total, 114 participants were recruited to the study but only 71 completed the study in the timescale for this PhD. The overall completion was 62.3%

As shown in Figure 7, there were originally 65 participants in the treatment group, but 14 discontinued treatment for reasons including lack of cooperation during treatment (n=11), moved to a different orthodontic practice (n=1), stopped treatment due to generalized root resorption identified during treatment (n=1) and stopped treatment due to trauma to a central incisor (n=1). Additionally, 15 participants did

not complete the functional appliance phase of treatment in the time scale of this study. Therefore data was available for 36 patients in the treatment group. The potential bias as a result of the losses to follow-up will be discussed later in the dissertation.

In the control group, 49 participants were recruited; one was lost to follow-up and 13 participants repeatedly cancelled appointments or had not been reviewed within the timescale of the study. This meant that 35 patients had data available at both T1 and T2.

Overall, these who completed the study were representative of the total group recruited as described in the next section.

3.3.2 Demographic data for all patients recruited to the study

Gender	Group				Total
	Treatment		Control		
	No.	%	No.	%	
Female	35	53.8	30	61.2	65
Male	30	46.2	19	38.8	49
Total	65	100.0	49	100.0	114

Table 39: Gender distribution in the treatment and control groups at T1

With regard to the gender distribution of the participants in the treatment group, there were more females (53.8%) than males (46.2%) and a similar observation was made in the control group, (61.2% and 38.8%, respectively). Details are given in Table 39.

Gender	Group				Total	
	Treatment (n=65)		Control (n=49)			
	Mean	SD	Mean	SD	Mean	SD
Female	12.00	1.37	11.10	1.01	11.58	1.29
Male	12.40	1.04	11.83	1.20	12.19	1.12
Total	12.18	1.24	11.37	1.13	11.83	1.25

Table 40: Age (in years) of the treatment and control group participants at T1

The age range recruited was from 10 to 14 years in both groups therefore all analyses and conclusions drawn are restricted to this age range. The mean age of the participants in the treatment and control groups are shown in Table 40. The mean age of female participants in the treatment group was 12.0 years and of the males was 12.4 years. The mean ages in the control group were 11.1 years (females) and 11.83 years (males). The overall mean age in the treatment group was greater than in the control group and this was significant when analysed using an independent sample t-test ($p < 0.001$).

3.3.3 Comparison of those participants who completed the study in both groups

Gender	Group				Total
	Treatment (n=36)		Control (n=35)		
	No.	%	No.	%	
Female	19	52.8	22	62.9	41
Male	17	47.2	13	37.1	30
Total	36	100.0	35	100.0	71

Table 41: Gender distribution in the treatment and control groups for those patients who completed the study

There were 71 participants who completed the study, 36 in the treatment group and 35 in the control group. With regard to the gender distribution of the participants in the treatment group, 52.8% were female and 47.2% male. In the control group, there were 62.9% females and 37.1% males. Therefore, there was a gender imbalance, although this was not significant ($p=0.27$) (Table 41).

Gender	Group				Total	
	Treatment (n=36)		Control (n=35)			
	Mean	SD	Mean	SD	Mean	SD
Female	12.37	1.26	11.14	1.04	11.71	1.29
Male	12.47	1.07	12.00	1.23	12.27	1.14
Total	12.42	1.16	11.46	1.17	11.94	1.25

Table 42: Mean and SD of age (in years) for the treatment and control groups for those patients who completed the study

The mean ages (at the start of treatment) of those participants who completed the study are shown in Table 42. The mean ages in the treatment group were 12.37 years and 12.47 years for females and males, respectively. In the control group, the mean ages were 11.14 years and 12.0 years for females and males. Again, It is of note that the mean age for the treatment group was significantly higher than that of

the control group ($p<0.001$). This is also illustrated in the box and whisker plot below (Figure 8).

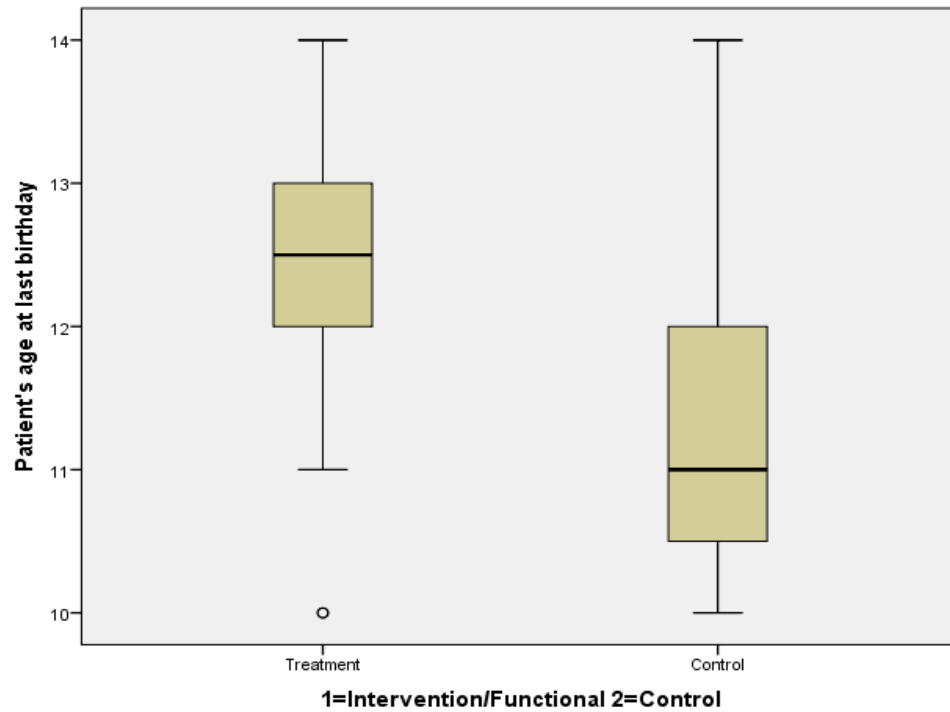


Figure 8: Box and whisker plot showing the ages of those participants who completed the study in both groups

3.3.4 Analysis of demographic data for those participants who completed the study compared with those who did not (Table 43)

When participants are lost from a study, there is potential for bias especially when a large number of participants are lost to follow up, as in the treatment group. It was therefore important to compare the demographic characteristics for those who completed the study compared with those who did not.

To determine whether there was a difference in completion between the groups, a Chi-square test was undertaken. Although it appeared that there was a greater loss to follow-up in the treatment group, this did not reach significance ($p=0.08$).

Number of patients	Completion/Non-completion of study		
	Number who did not complete the study (%)	Number who completed the study (%)	Total
Treatment group	29 (44.62%)	36 (55.38%)	65
Control group	14 (28.57%)	35 (71.43%)	49
Total	43 (37.72%)	71 (62.28%)	114

Table 43: Comparisons between those who completed/ did not complete the study for both groups

Treatment group: Comparison of characteristics in those participants who did/ did not complete the study

The characteristics which were compared for the completion/ non-completion groups were age, gender, patient-perceived IOTN-AC category and the questionnaire scores for OASIS, the MSCS and SAS-A scales. The IOTN-AC was included as it was thought possible that those participants who felt their malocclusion was more severe may be more likely to complete treatment, thus potentially leading to bias.

	Did not complete the study (n=29)	Completed the study (n=36)
Mean age at recruitment (SD)	11.9 (1.29)	12.4 (1.16)
Median age at recruitment (Range)	12.0 (10 to 14)	12.5 (10 to 14)

Table 44: Comparison of the age (years) of the treatment group participants who completed the study compared with those who did not

In the treatment group, the median age at recruitment for those who did not complete the study was 12.0 years compared with 12.5 years for those who did complete the study. The difference in the distribution of age between the two groups was not statistically significant ($p=0.093$ using Mann Whitney test) (Tables 44 and 46).

Number of patients	Completion/Non-completion of study		
	Number who did not complete the study (%)	Number who completed the study (%)	Total
Female	16 (45.71%)	19 (54.29%)	35
Male	13 (43.33%)	17 (56.67%)	30
Total	29 (44.62%)	36 (55.38%)	65

Table 45: Comparison of gender for the treatment group participants who completed the study compared with those who did not

A Chi-square test showed that there were no significant gender differences between the group who completed the study and those who did not complete the study ($p>0.99$ with a continuity correction applied) (Table 45).

	Did not complete the study (n=29)	Completed the study (n=36)	p-value
Median OASIS scores (min- max score) at T1	13.00 (6 to 30)	15.00 (6 to 34)	0.137
Median MSCS scores (min- max score) at T1*	85.00 (60 to 100)	79.00 (48 to 98)	0.085
Median SAS-A scores (min- max score) at T1	31.00 (18 to 70)	39.00 (21 to 79)	0.121

Table 46: Mann-Whitney test results for the comparison of questionnaire scores at T1 for the treatment group participants who completed the study compared with those who did not (*NB: raw MSCS scores utilised for the analysis rather than standardised scores)

The data for the T1 questionnaire scores were not-normally distributed therefore analyses were undertaken using Mann-Whitney tests. The analyses showed there were no significant differences in the T1 scores between those who completed the study and those who did not (Table 46).

Number of patients	Completion/Non-completion of study		
	Number who did not complete the study (%)	Number who completed the study (%)	Total
IOTN-AC 1-5	25 (51.02%)	24 (48.98%)	49
IOTN-AC 6-10	4 (25%)	12 (75%)	16
Total	29 (44.62%)	36 (55.38%)	65

Table 47: Comparison of IOTN-AC for the treatment group participants who completed the study compared with those who did not

For the self-perceived IOTN-AC, a comparison between those who did/did not complete the study was undertaken using a Fisher's Exact Test (a Chi-squared test was not used because the expected number of participants was less than 5 in one of the cells), however, the difference was non-significant with $p=0.09$ (Table 47).

Control group: Comparison of characteristics in those participants who did/did not complete the study

	Did not complete the study (n=14)	Completed the study (n=35)
Mean age at recruitment (SD)	11.14 (1.03)	11.46 (1.17)
Median age at recruitment (Range)	11.00 (10 to 13)	11.00 (10 to 14)

Table 48: Comparison of the age of the control group participants who completed the study compared with those who did not

In the control group, the median age at recruitment for those who did not complete the study was 11.0 years which was the same as the median age in the control

group. The age distribution was not statistically significant different ($p=0.40$) using a Mann Whitney test (Table 48).

Number of patients	Completion/Non-completion of study		
	Number who did not complete the study (%)	Number who completed the study (%)	Total
Female	9 (29.03%)	22 (70.97%)	31
Male	5 (27.78%)	13 (72.22%)	18
Total	14 (28.57%)	35 (71.43%)	49

Table 49: Comparison of gender for the control group participants who completed the study compared with those who did not

A Chi-square test was used to assess gender differences between those who completed/did not complete the study and this showed that there was no significant gender difference between the two groups ($p>0.99$ with continuity correction applied) (Table 49).

	Did not complete the study (n=14)	Completed the study (n=35)	p-value
Median OASIS scores (min-max score) at T1	13.00 (5 to 35)	13.00 (6 to 29)	0.438
Median MSCS scores (min-max score) at T1*	84.50 (48 to 94)	83.00 (62 to 98)	0.690
Median SAS-A scores (min-max score) at T1	34.00 (21 to 84)	36.00 (23 to 74)	0.547

Table 50: Mann-Whitney test results for the comparison of questionnaire scores at T1 for the control group participants who completed the study compared with those who did not (*NB: raw MSCS scores utilised for the analysis rather than standardised scores)

The data for the questionnaire scores at T1 were not-normally distributed therefore analyses were undertaken using Mann-Whitney tests. The analyses showed there were no significant differences in the T1 scores between those who completed the study and those who did not (Table 50).

Number of patients	Completion/Non-completion of study		
	Number who did not complete the study (%)	Number who completed the study (%)	Total
IOTN 1-5	12 (35.29%)	22 (64.71%)	34
IOTN 6-10	2 (13.33%)	13 (86.67%)	15
Total	14 (28.57%)	35 (71.43%)	49

Table 51: Comparison of IOTN-AC for the control group participants who completed the study compared with those who did not

For the self-perceived IOTN-AC, a Fisher's Exact Test was used to compare the data for those who did/did not complete the study and the difference was non-significant at $p=0.17$ (Table 51).

3.3.5 Analysis of data for those participants who completed the study (Completed both T1 and T2 questionnaires)

Index of Orthodontic Treatment Need – Aesthetic Component scores at T1 and T2 (Figures 9 and 10)

IOTN-AC scores are categorical and in this results section are therefore presented as bar charts. Comparison of the two graphs between T1 and T2 shows a tendency for ratings to move towards the lower end of the scale at T2 and this was evident for both groups. It is interesting that the control group IOTN-AC decreased also, despite the fact that the control group had not undergone any treatment.

Further analysis of the IOTN-AC data would potentially be interesting but was not the focus of the current study. The IOTN-AC was primarily included as part of the OASIS but was subsequently excluded from this component as it was felt to be inappropriate to analyse it in conjunction with the OASIS scores.

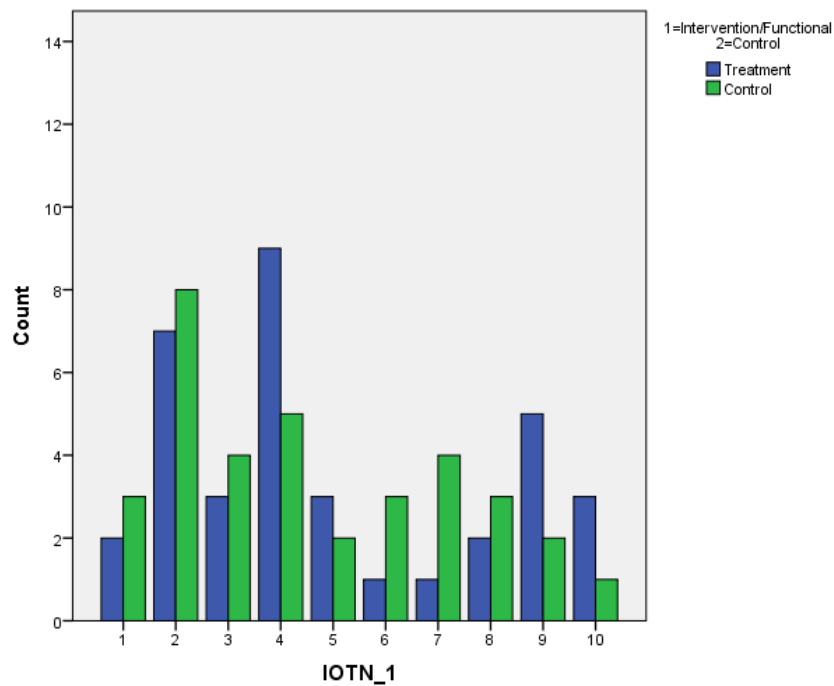
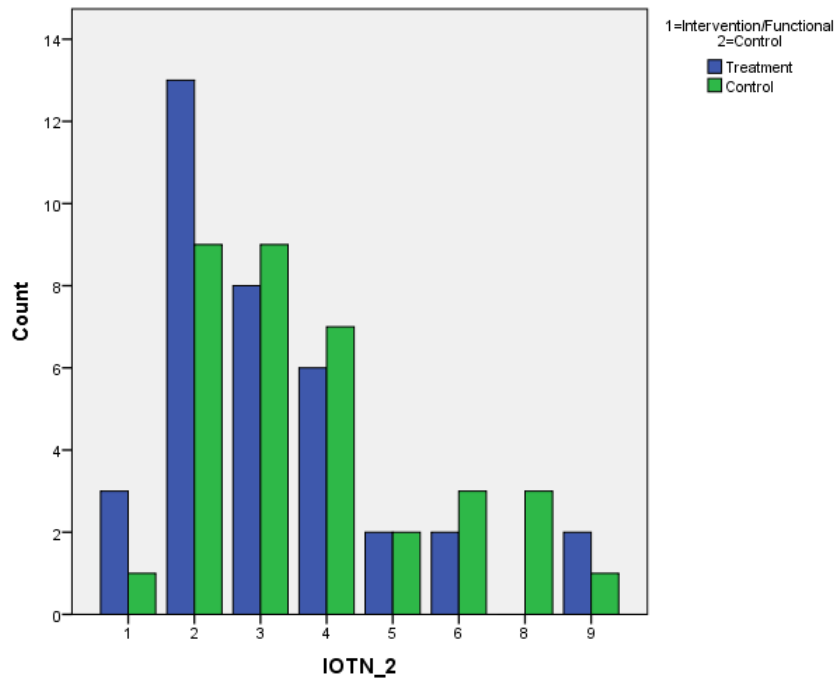


Figure 9: IOTN-AC categories at T1 for those who completed the study



NB: There were no observations in categories 7 or 10 at T2

Figure 10: IOTN-AC categories at T2 for those who completed the study

The first part of this analysis utilising data from those patients who completed T1 and T2 questionnaires aimed to address the primary research question: Does orthodontic treatment being undertaken for the treatment of prominent upper front teeth (Class II division 1) have social benefits?

Oral Aesthetic Subjective Impact Scale (OASIS) questionnaire scores at T1 and T2

		Mean (SD)	Median (min to max)
Treatment (n=36)	OASIS T1	17.00 (7.56)	15.00 (6 to 34)
	OASIS T2	14.11 (7.14)	13.00 (5 to 30)
	T1-T2 Difference	2.89 (6.68)	2.5 (-12 to 27)
Control (n=35)	OASIS T1	15.00 (7.00)	13.00 (6 to 29)
	OASIS T2	15.06 (7.84)	14.00 (5 to 33)
	T1-T2 Difference	-0.06 (5.79)	1.00 (-13 to 15)

Table 52: OASIS scores at T1 and T2 for those who completed the study

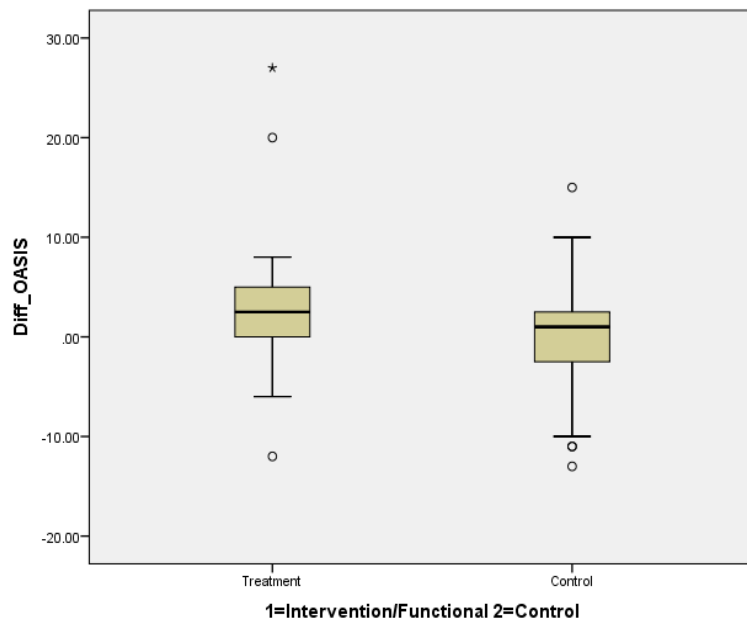


Figure 11: Box and whisker plot showing the T1-T2 difference in OASIS scores for the two groups

The OASIS scores at T1 were slightly higher for the treatment group than the control group but at T2, the control group score were slightly higher than the treatment group. The T1-T2 differences were felt to be sufficiently normally distributed to use an independent samples *t*-test and this showed no significant difference between the two groups ($p=0.051$). Although not statistically significant, the treatment group showed, on average, a greater change between the T1 and T2 questionnaires than the control group and the difference for the treatment group was in a direction which indicated that concern regarding the dentition was reduced. However, the substantial spread of the data, including the outliers, should be noted from the boxplot (Table 52 and Figure 11).

**Univariable linear regressions for T2 OASIS score (5 separate regressions)
(Table 53)**

Univariable regression analyses were undertaken to explore the relationship between the OASIS T2 scores and group (treatment or control), age, OASIS T1 scores, gender and patient perceived IOTN-AC category at T2 (using the binary classification as described earlier). This applies for subsequent sections also.

Independent Variables	Unstandardized coefficients	95.0% confidence interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 -Treatment</i> <i>2 - control</i>	0.946	-2.602	4.494	0.596
Age	0.139	-1.290	1.569	0.846
OASIS T1 score	0.639	0.448	0.830	<u><0.001</u>
Gender <i>0 - Female</i> <i>1 - Male</i>	-1.577	-5.156	2.001	0.382
IOTN-AC category at T2 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	3.189	-1.663	8.042	0.194

Table 53: Univariable regression analysis for the OASIS questionnaire at T2 for those participants who completed the study

Although only one variable (OASIS T1 score) was significant in the univariable analyses, a decision was made to undertake a multivariable analysis. This was in order to include the T1 covariate score alongside the other variables, statistical advice suggested that the multivariable approach was potentially superior to the univariable approach. This also applies in subsequent sections.

The conclusions drawn regarding significance/non-significance are similar in the univariable and multivariable regressions, therefore conclusions are drawn from the multivariable regression analysis following the next table.

Multivariable linear regression for T2 OASIS score (Table 54)

Independent Variables	Unstandardized coefficients	95.0% confidence interval		p-value
	B	Lower bound	Upper bound	
(Constant)	-4.650	-21.960	12.660	0.593
Group <i>1 - Treatment</i> <i>2 - Control</i>	2.467	-0.605	5.540	0.114
Age	0.443	-0.794	1.680	0.477
OASIS T1 score	0.648	0.454	0.844	<0.001
Gender <i>0 - Female</i> <i>1 - Male</i>	-0.793	-3.692	2.106	0.587
IOTN-AC category at T2 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	1.350	-2.556	5.256	0.492

Table 54: Multivariable regression analysis for the OASIS questionnaire at T2 for those participants who completed the study

The analysis for the OASIS questionnaire showed that group did not have a significant effect on the OASIS score at T2, when the other variables were accounted for. The B coefficient shows that the OASIS T2 score was higher in the control group by an average of 2.467 points when all other variable were accounted for, which indicates greater concern regarding the dentition in the control group than in the treatment group, but this was not significant when all other variable were accounted for ($p=0.114$).

There was a significant effect for OASIS T1 score; as the OASIS T1 score increased by 1 point, the OASIS 2 score was, on average, 0.648 points higher. There was however no significant effect for age, gender or the patient perceived IOTN-AC at T2. Regarding age, the analysis showed that as age increased by 1 year, the OASIS T2 score increased on average by 0.443 points. For gender, males showed scores which were 0.793 points less, on average, than those of females, after adjusting for the other variables. Patients with a higher IOTN-AC category had scores which were greater by, on average, 1.350 points. It should, however, be noted that a relatively small number of patients (n=11 in total) had an IOTN-AC of 6 to 10 at T2 and this limits the conclusions which can be drawn.

Multidimensional Self Concept Scale (MSCS) scores at T1 and T2 (raw scores)

		Mean (SD)	Median (min to max)
Treatment (n=36)	MSCS T1	79.03 (10.01)	79.00 (48 to 98)
	MSCS T2	81.72 (8.33)	82.00 (66 to 98)
	T1-T2 Difference	-2.69 (7.69)	-1.50 (-23 to 8)
Control (n=35)	MSCS T1	82.51 (9.12)	83.00 (62 to 98)
	MSCS T2	84.91 (7.99)	83.00 (72 to 99)
	T1-T2 Difference	-2.40 (8.21)	-3.00 (-21 to 14)

Table 55: MSCS raw scores at T1 and T2 for those who completed the study

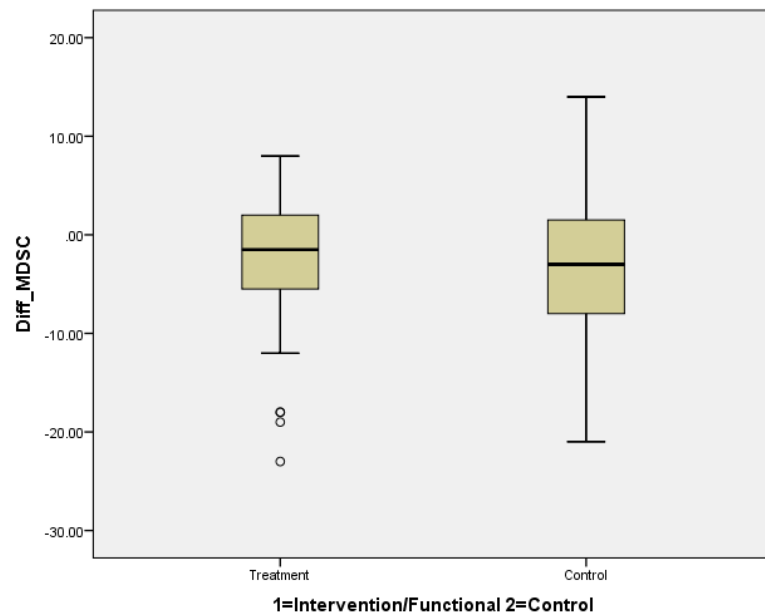


Figure 12: Box and whisker plot showing the T1-T2 difference in MSCS raw scores for the two groups

The MSCS raw scores were slightly lower for the treatment group than the control group at both T1 and T2 but the scores for both groups increased at T2. This suggests slightly increased self-concept. When the T1-T2 differences were analysed using an independent samples t-test, there was no significant difference between the two groups ($p=0.88$). Again, the wide standard deviations, relative to the mean T1-T2 differences, should be noted (Table 55 and Figure 12).

Univariable linear regressions for T2 MSCS scores (5 separate regressions)
(Table 56)

Independent Variables	Unstandardized coefficients	95% confidence interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 - Treatment</i> <i>2 - control</i>	3.192	-0.675	7.059	0.104
Age	-0.682	-2.258	0.895	0.391
MSCS T1 score	0.532	0.371	0.692	<u><0.001</u>
Gender <i>0 - Female</i> <i>1 - Male</i>	-0.050	-4.040	3.939	0.980
IOTN-AC category at T2 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	-0.350	-5.796	5.096	0.898

Table 56: Univariable regression analysis for the MSCS questionnaire at T2 for those participants who completed the study

The conclusions drawn regarding significance/non-significance are similar in the univariable and multivariable regressions, therefore conclusions are drawn from the multivariable regression following the next table.

Multivariable linear regression for T2 MSCS scores (Table 57)

Independent Variables	Unstandardized coefficients	95% confidence interval		p-value
	B	Lower bound	Upper bound	
(Constant)	44.356	21.914	66.798	<0.001
Group 1 -Treatment 2 - Control	1.058	-2.435	4.551	0.547
Age	-0.473	-1.873	0.928	0.503
MSCS T1 score	0.526	0.359	0.693	<0.001
Gender 0 - Female 1 - Male	1.329	-1.951	4.609	0.421
IOTN-AC category at T2 0 – IOTN-AC 1 to 5 1 – IOTN-AC 6 to 10	-0.218	-4.605	4.169	0.921

Table 57: Multivariable regression analysis for the MSCS questionnaire at T2 for those participants who completed the study

This analysis showed that group did not significantly affect MSCS T2 raw score, when other variables were accounted for. The control group showed T2 scores which were, on average, 1.058 points higher than the treatment group which indicates better self-concept in the control group, but this was not significant ($p=0.55$). Interestingly, the coefficient in the univariable analysis suggested a greater difference between the treatment and control groups (3.192 points) but this group effect was modified when other variables were included in the multivariable linear regression equation.

There was a significant effect for MSCS T1, as the T1 score increased by 1 point, MSCS T2 increased by 0.526 on average and this was a significant finding ($p<0.001$).

There were no significant age, gender, or IOTN-AC effects and the coefficients (and therefore the effect size) were small for all variables. For the age, as age increased by 1 year, the MSCS T2 decreased by 0.473 points on average. Regarding gender, self-concept in males was, on average, 1.329 points higher than in females. For IOTN-AC, those who had a higher IOTN-AC showed very slightly lower scores but this was not significant and the difference was very small.

Multidimensional Self Concept Scale standardised (S) scores at T1 and T2

The MSCS raw scores were standardised using the Appendix in the MSCS manual (Braken, 1992). This allows scores to be compared with those from other studies (Table 58).

		Mean (SD)	Median (min to max)
Treatment (n=36)	MSCS (S) T1	105.86 (14.99)	105 (70 to 141)
	MSCS (S) T2	109.47 (13.43)	109.00 (86 to 141)
	T1-T2 Difference	-3.61 (11.11)	-3.00 (-32 to 13.00)
Control (n=35)	MSCS (S) T1	110.86 (14.34)	111.00 (82 to 141)
	MSCS (S) T2	114.94 (14.08)	111.00 (94 to 143)
	T1-T2 Difference	-4.09 (13.75)	-5.00 (-30.00 to 23.00)

Table 58: MSCS standardised scores at T1 and T2 for those who completed the study

When the standardised scores were compared with those shown in Table 35, both the treatment and control groups had average self-concept at both T1 and T2.

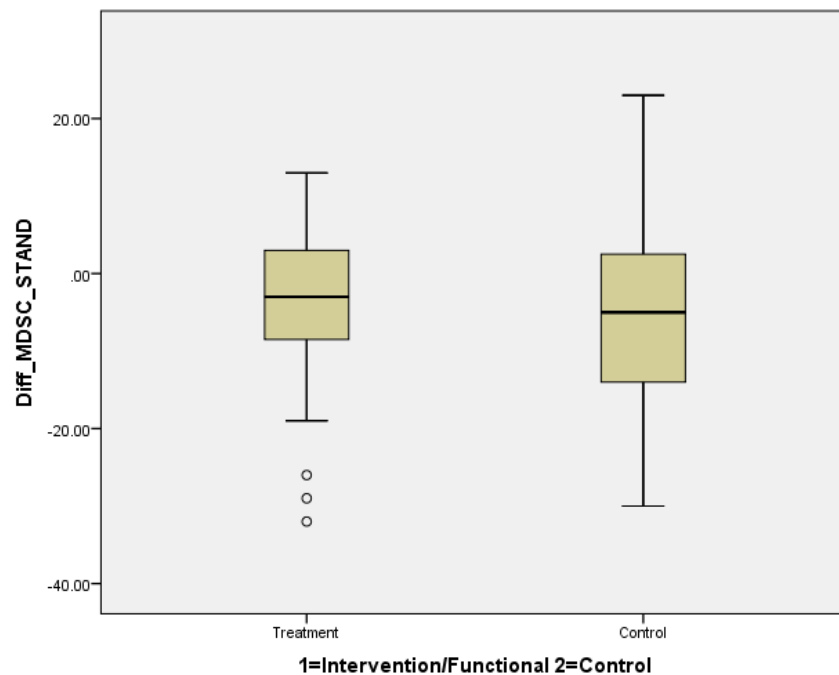


Figure 13: Box and whisker plot showing the T1-T2 differences for the MSCS standardised scores for the two groups

As anticipated, when the T1-T2 standardised differences were analysed using an independent samples t-test, there was no significant difference between the two groups with an almost identical p-value to that obtained for the raw scores ($p=0.873$) (Figure 13).

Multivariable linear regression for MSCS (S) T2 scores (Table 59)

Independent Variables	Unstandardized coefficients	95% confidence interval		p-value
	B	Lower bound	Upper bound	
(Constant)	54.821	18.333	91.308	0.004
Group 1 -Treatment 2 - Control	2.053	-3.762	7.867	0.483
Age	-0.827	-3.164	1.510	0.482
MSCS T1 score	0.584	0.402	0.766	<u><0.001</u>
Gender 0 - Female 1 - Male	2.357	-3.119	7.833	0.393
IOTN-AC category at T2 0 – IOTN-AC 1 to 5 1 – IOTN-AC 6 to 10	-0.633	-7.961	6.695	0.864

Table 59: Multivariable regression analysis for the MSCS questionnaire with standardised scoring at T2 for those participants who completed the study

Only the multivariable analysis was undertaken for the standardised scores as the basic outcome of the analysis, in terms of significance/non-significance, would not change from that for the raw scores. As anticipated, this analysis showed that group (treatment or control) did not significantly affect the MSCS standardised T2 score, when other variables were accounted for. The control group showed standardised scores at T2 which were, on average, 2.053 points higher than the treatment group, but this was not significant.

There was a significant effect for MSCS T1, as the T1 standardised score increased by 1 point, the standardised score at T2 increases by 0.584 and this was a significant finding ($p<0.001$).

There were no significant age, gender, or IOTN-AC effects, as in the analysis of the raw data.

Social Anxiety Scale for Adolescents (SAS-A) scores at T1 and T2

		Mean (SD)	Median (min to max)
Treatment (n=36)	SAS-A T1	39.83 (12.50)	39.00 (21 to 79)
	SAS-A T2	36.17 (10.65)	34.50 (19 to 63)
	T1-T2 Difference	3.67 (9.22)	4.00 (-23 to 19)
Control (n=34)*	SAS-A T1	38.21 (12.14)	36.00 (23 to 74)
	SAS-A T2	34.79 (9.43)	34.50 (18 to 62)
	T1-T2 Difference	3.41 (9.46)	2.50 (-13 to 36)
NB: There was data missing for one control group patient for the SAS T1 questionnaire, therefore data is for one fewer person than the other analyses			

Table 60: SAS-A scores at T1 and T2 for those who completed the study

The average SAS-A scores were slightly higher for the treatment group than the control group both at T1 and T2. Median scores were in the normal social anxiety range at T1 (see Table 36) but at T2, the scores were in the low social anxiety range for both groups (less than 36). The average scores for both groups reduced at T2 suggesting reduced social anxiety, however when the T1-T2 differences were analysed using an independent samples *t*-test, there was no significant difference between the two groups ($p=0.91$). Again, the wide standard deviations, relative to the mean T1-T2 differences, should be noted (Table 60 and Figure 14).

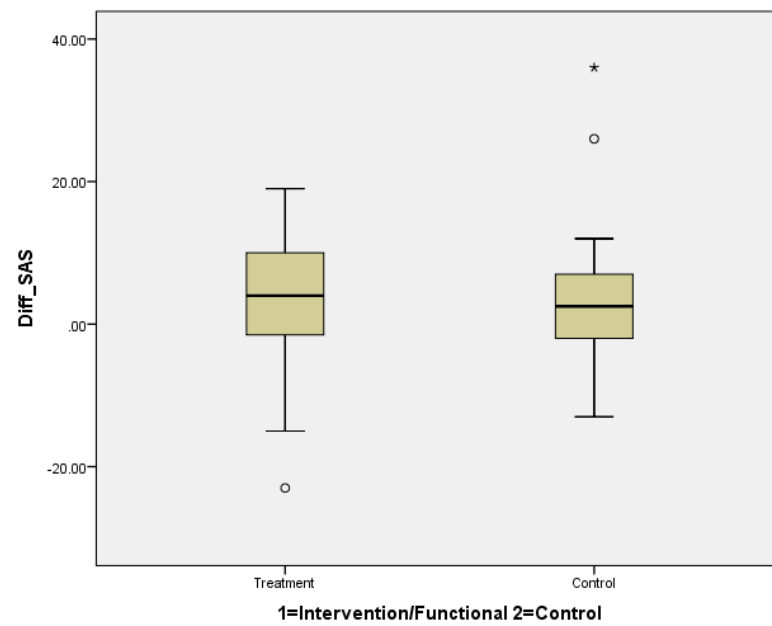


Figure 14: Box and whisker plot showing the T1-T2 difference in SAS scores for the two groups

Univariable linear regressions for SAS-A scores at T2 (5 separate regressions)
(Table 61)

Independent Variables	Unstandardized coefficients	95% confidence interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 -Treatment</i> <i>2 - control</i>	-1.567	-6.318	3.184	0.513
Age	-0.523	-2.435	1.389	0.587
SAS-A T1 score	0.548	0.402	0.695	<u><0.001</u>
Gender <i>0 - Female</i> <i>1 - Male</i>	-3.396	-8.150	1.358	0.159
IOTN-AC category at T2 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	2.976	-3.571	9.522	0.368

Table 61: Univariable regression analysis for the SAS-A questionnaire at T2 for those participants who completed the study

The conclusions drawn regarding significance/non-significance are similar in the univariable and multivariable regressions, therefore conclusions are drawn from the multivariable regression following the next table.

Multivariable linear regression for SAS-A scores at T2 (Table 62)

Model	Unstandardized coefficients	95% confidence interval		p-value
	B	Lower bound	Upper bound	
(Constant)	32.079	9.774	54.384	0.006
Group 1 - Treatment 2 - Control	-1.860	-5.756	2.035	0.344
Age	-1.214	-2.828	0.400	0.138
SAS-A T1 score	0.546	0.396	0.695	<0.001
Gender 0 - Female 1 - Male	-1.669	-5.443	2.104	0.380
IOTN-AC category at T2 0 – IOTN-AC 1 to 5 1 – IOTN-AC 6 to 10	0.674	-4.330	5.678	0.789

Table 62: Multivariable regression analysis for the SAS-A questionnaire at T2 for those participants who completed the study

This analysis indicated that group (treatment or control) did not significantly affect the SAS-A T2 score, when the other variables were accounted for ($p=0.344$). The control group had SAS-A scores which were, on average, 1.860 points lower than the treatment group and this indicates lower social anxiety in the control group at T2, but this did not reach significance.

As the SAS-A T1 score increased by 1 point, the SAS-A T2 score increased by 0.546 points on average and this was a significant finding ($p<0.001$). There were no significant age, gender or IOTN-AC effects. Regarding age, the analysis showed that as age increased by 1 year, SAS-A T2 decreased by 1.214 points on average. For gender, social anxiety in males was 1.669 points less, on average, than in females. This was a lower effect size than seen in the univariable analysis but neither finding was significant. For patient perceived IOTN-AC, those with a higher

IOTN-AC had slightly higher SAS-A scores (0.674). Again this was a smaller effect size than in the univariable analysis but was non-significant in both analyses.

3.3.6. Analysis of T1 data for all participants recruited to the study (n=114)

The analyses presented in this section analysed the data for all participants recruited to the study and investigated the secondary research question regarding whether there was a significant difference in terms of social impacts for the treatment and control groups at the time of recruitment (T1).

The variables included in the regression were group (treatment or control), age, gender and the patient's own subjective IOTN-AC score at T1. As in the previous section, initially univariable regressions were undertaken and this was followed by a further exploratory multivariable regression.

Oral Aesthetic Subjective Impact Scale: T1 data

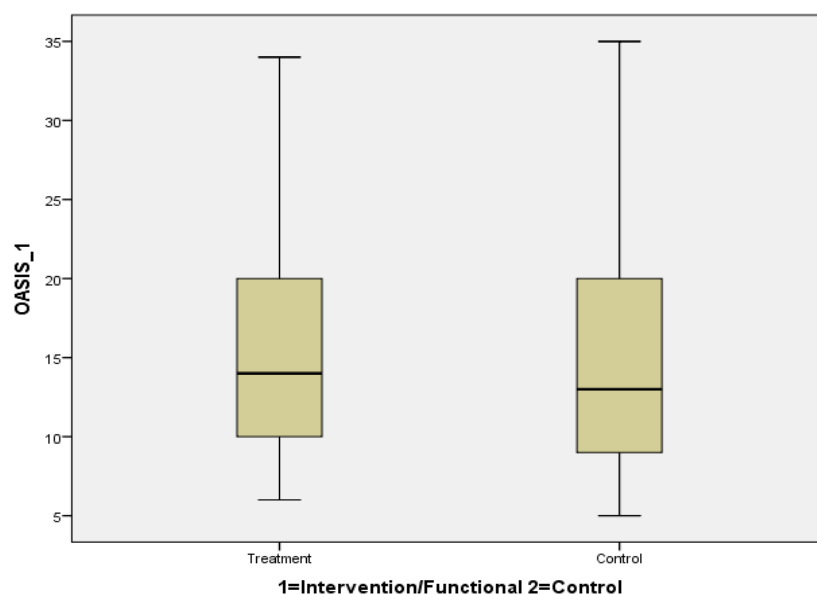


Figure 15: Box and whisker plot showing OASIS scores at T1 for the treatment and control groups

	Mean (SD)	Median (min to max)
Treatment (n=65)	15.68 (7.10)	14.00 (6 to 34)
Control (n=49)	14.71 (7.36)	13.00 (5 to 35)

Table 63: Descriptive data for the OASIS questionnaire for all participants at T1

The box and whisker plot shows that the data was not normally distributed (Figure 15) therefore comparisons between groups were made using a Mann-Whitney U-test; this showed no significant difference between the 2 groups for the OASIS questionnaire at T1 ($p=0.382$) (Table 63).

Univariable linear analyses for OASIS scores at T1 (4 separate regressions)
(Table 64)

Univariable analysis was then undertaken to assess the effects of the four individual variables on the OASIS score at T1.

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 - Treatment</i> <i>2 - Control</i>	-0.963	-3.667	1.741	0.482
Age (years)	0.799	-0.265	1.862	0.140
Gender <i>0 - Female</i> <i>1 - Male</i>	1.273	-1.434	3.980	0.354
IOTN-AC at T1 <i>0 - IOTN-AC 1 to 5</i> <i>1 - IOTN-AC 6 to 10</i>	4.291	1.384	7.197	<u>0.004</u>

Table 64: Univariable analyses investigating the effects of four individual explanatory variables on the OASIS score at T1

The univariable analyses showed that the only significant explanatory variable was the self-perceived IOTN-AC category, with those in IOTN-AC 6 to 10 having OASIS scores which were, on average, 4.291 points higher than those in IOTN-AC 1 to 5. Therefore those who assessed their dental aesthetics as being poorer on the IOTN-AC also had greater concern on the OASIS questionnaire.

The other results are similar to those in the multivariable regression so will be considered further after the next table.

Multivariable linear analysis for OASIS scores at T1 (Table 65)

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 - Treatment</i> <i>2 - Control</i>	-0.525	-3.285	2.235	0.707
Age (years)	0.797	-0.327	1.921	0.163
Gender <i>0 - Female</i> <i>1 - Male</i>	0.583	-2.117	3.283	0.670
IOTN-AC at T1 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	4.476	1.558	7.394	<u>0.003</u>

Table 65: Multivariable linear regression analysis investigating the effects of four explanatory variables on the OASIS score at T1

The multivariable analysis confirmed the findings of the univariable analyses. There were no significant group, age or gender effects. The control group had scores which were, on average, 0.525 points lower than the treatment group having accounted for all other variables. This suggests less concern regarding dental aesthetics but was a very small difference and did not reach significance ($p=0.71$). As age increased, so did the OASIS score, by 0.797 points for every year increase in age. Males also gave higher scores than females by 0.583 points.

The only variable significantly affecting the score was the IOTN-AC, with those in IOTC-AC 6 to 10 having OASIS scores which were, on average, 4.476 points higher than those in IOTN-AC 1 to 5 ($p=0.003$). Therefore those who assessed their dental aesthetics as being poorer on the IOTN-AC also had greater concern on the OASIS questionnaire.

Multidimensional Self Concept Scale (MSCS) scores: T1 data

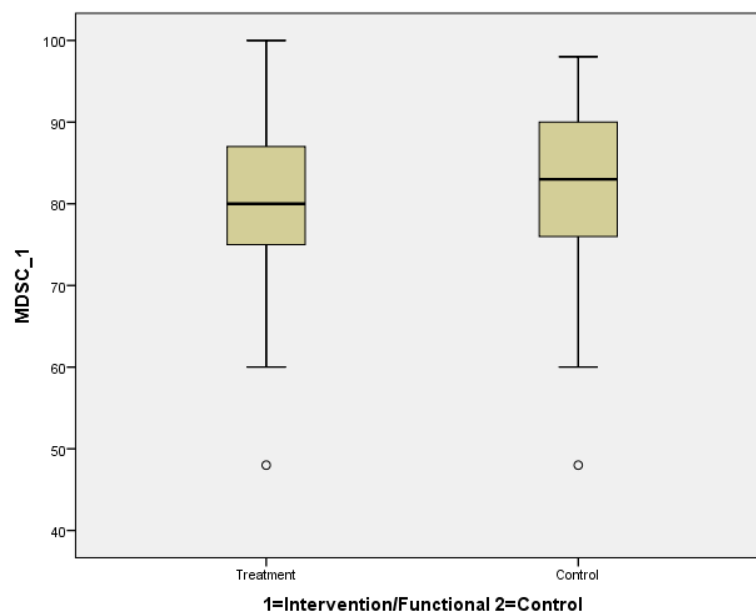


Figure 16: Box and whisker plot showing MSCS scores at T1 for the treatment and control groups

	Mean (SD)	Median (Min to Max)
Treatment (n=65)	80.86 (10.34)	80.00 (48 to 100)
Control (n=49)	81.78 (10.39)	83.00 (48 to 98)

Table 66: MSCS questionnaire scores (raw data) for all participants at T1

The median score for the MSCS was 80.00 for the treatment group and 83.00 for the control group. The data for the treatment group was relatively normally distributed, although there was some skewness for the control group, therefore comparison between groups was made using a Mann-Whitney test; this showed no

significant difference between the 2 groups for the MSCS questionnaire ($p=0.41$) (Table 66 and Figure 16).

Univariable linear regression analyses for MSCS scores at T1 (4 separate regressions) (Table 67)

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 - Treatment</i> <i>2 - Control</i>	0.914	-2.970	4.798	0.642
Age	0.033	-1.508	1.574	0.966
Gender <i>0 - Female</i> <i>1 - Male</i>	-2.527	-6.396	1.343	0.198
IOTN-AC at T1 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	-4.780	-9.012	-0.548	<u>0.027</u>

Table 67: Univariable analyses investigating the effects of four individual explanatory variables on the MSCS score at T1

The univariable analyses showed that the only significant explanatory variable was the self-perceived IOTN-AC category, with those in IOTC-AC 6 to 10 having MSCS scores which were, on average, 4.780 points less on the MSCS, and therefore showing less positive self-concept than those in IOTN-AC categories 1 to 5 ($p=0.027$). The other findings will be discussed with reference to the multivariable regression.

Multivariable linear regression analysis for MSCS scores at T1 (Table 68)

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 -Treatment</i> <i>2 - Control</i>	1.206	-2.841	5.253	0.556
Age	-0.292	-1.356	1.940	0.726
Gender <i>0 - Female</i> <i>1 - Male</i>	-2.431	-6.390	1.529	0.226
IOTN-AC at T1 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	-4.705	-8.984	-0.426	<u>0.031</u>

Table 68: Multivariable linear regression analysis investigating the effects of four explanatory variables on the MSCS score at T1

The univariable findings were confirmed in the multivariable linear regression, with IOTN-AC category being the only significant variable ($p=0.031$), with those in IOTC-AC 6 to 10 having MSCS scores which were 4.705 points lower than those in IOTN-AC 1 to 5, and therefore showing less positive self-concept than those in IOTN-AC categories 1 to 5.

There were no significant group, age or gender effects. The control group had scores which were, on average, 1.206 points higher than the treatment group, suggesting more positive self-concept in the control group patients, but this was a small difference and did not reach statistical significance ($p=0.556$). As age increased, MSCS scores reduced but only by a very small amount (0.292 for every year increase in age). Males had lower scores than females by 2.431 points, on average, suggesting poorer self-concept, but again this did not reach significance ($p=0.226$).

Social Anxiety Scale for Adolescents (SAS-A): T1 data

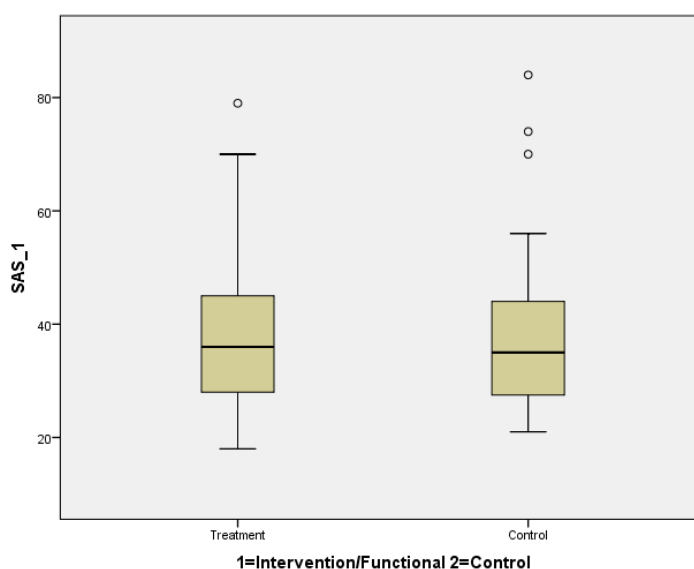


Figure 17: Box and whisker plot showing SAS-A scores at T1 for the treatment and control groups

	Mean (SD)	Median (Min to max)
Treatment (n=65)	37.92 (12.75)	36.00 (18 to 79)
Control (n=49)	38.13 (13.37)	35.00 (21 to 84)

Table 69: SAS-A questionnaire scores for all participants at T1

The mean and median scores were at the lower end of the score range (Table 69), when this is compared with the standard score ranges in Table 36. The median scores suggest normal levels of social anxiety in the treatment group and low social anxiety in the control group (cut-off=36). There were some outliers in this boxplot

(Figure 17), therefore comparison between groups was made using a Mann-Whitney U-test; this showed no significant difference between the 2 groups for the SAS-A questionnaire ($p=0.96$).

Univariable linear regression analyses for SAS-A T1 data (4 separate regressions) (Table 70)

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 - Treatment</i> <i>2 - Control</i>	0.202	-4.707	5.111	0.935
Age	1.153	-0.788	3.094	0.242
Gender <i>0 - Female</i> <i>1 - Male</i>	-1.837	-6.748	3.075	0.460
IOTN-AC at T1 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	2.030	-3.452	7.512	0.464

Table 70: Univariable analyses investigating the effects of four individual explanatory variables on the SAS-A score at T1

The univariable analyses showed that there were no significant explanatory variables for the Social Anxiety Scale. Further discussion can be found after the multivariable regression data.

Multivariable linear regression analysis (Table 71)

Independent Variables	Unstandardized coefficients	95% Confidence Interval		p-value
	B	Lower bound	Upper bound	
Group <i>1 -Treatment</i> <i>2 - Control</i>	1.077	-4.091	6.244	0.680
Age	1.627	-0.492	3.746	0.131
Gender <i>0 - Female</i> <i>1 - Male</i>	-2.835	-7.933	2.263	0.273
IOTN-AC at T1 <i>0 – IOTN-AC 1 to 5</i> <i>1 – IOTN-AC 6 to 10</i>	2.293	-3.209	7.796	0.411

Table 71: Multivariable linear regression analysis investigating the effects of four explanatory variables on the SAS-A score at T1

The univariable findings were confirmed in the multivariable regression, with none of the explanatory variables reaching statistical significance.

The control group had scores which were, on average, 1.077 points higher than the treatment group, but this difference was not statistically significant ($p=0.680$). As age increased, so did the SAS-A score, by an average of 1.627 points for every year. Males gave lower scores than females, by an average of 2.835 points suggesting lower social anxiety, but again this did not reach significance ($p=0.273$). Those in the higher IOTN-AC group also showed higher SAS-A scores (by 2.293 points) but this was not significant ($p=0.411$).

3.4 Discussion

The main reasons cited for undergoing orthodontic treatment are aesthetic and psycho-social factors. Studies have suggested that, among those who seek orthodontic treatment for malocclusion, 80% do so for aesthetic reasons and that may also have a positive social impact (Birkeland *et al.*, 2000; Bernabé *et al.*, 2006). A study some time ago found that nearly 50% of children in the USA would benefit from treatment of malocclusion and out of these, approximately 5% of patients would be considered “seriously handicapped” as a result of their malocclusion (Kelly and Harvey, 1977). Treatment of a malocclusion may therefore lead to improved dental and facial appearance, but also enhanced body image and social acceptance. However, the extent of the impact of orthodontic treatment on social factors is not clear.

In a longitudinal study by Shaw *et al.* (2007), participants with a prior need for orthodontic treatment reported better dental alignment and greater satisfaction with the appearance of their teeth. However, the treatment had little positive impact on psychological health and quality of life in adulthood and the study concluded that lack of orthodontic treatment when there was a need did not lead to psychological difficulties in later life.

Orthodontic treatment using functional appliances is often started at early age. Treatment at this early stage in a child's maturation may benefit them by increasing their social acceptance and preventing, or reducing, the development of poor self-concept and high levels of social anxiety. However, there is little evidence to support an association between absence of malocclusion and measurably higher self-concept or lower social anxiety (Helm *et al.*, 1985; Trulsson *et al.*, 2002; O'Brien, 2006; 2009). The current study was therefore conducted to investigate the social effects of malocclusion and orthodontic treatment in adolescent patients undergoing functional appliance treatment for Class II division 1 malocclusions, whilst controlling for confounders and maturational changes.

3.4.1 Discussion of methodology

Challenges during the study:

Participant follow-up/non-completion:

There is a high risk of bias due to non-completion of the study by participants. A number of the treatment group participants did not complete their functional appliance treatment or the treatment lasted longer than had been anticipated. Follow-up of patients in the control group also proved difficult and a number of patients repeatedly cancelled appointments and could not be followed up in the timescale of this study. Loss to follow up in longitudinal studies may result in the final sample size not being attained, however the sample size was increased by 40% to allow for this hence the necessary sample size was achieved. Interestingly, the dropout was 37.7%, which is very close to the 40% allowed for in the sample size calculation. Those who did not complete the study were also analysed to establish whether there were any differences between the completors and non-completors and no significant differences were identified for the variables considered.

A large number of orthodontic longitudinal studies have showed a high dropout; in the Cardiff study with a follow-up period for 20 years, there was 70% loss to follow-up (Kenealy *et al.*, 2007; Shaw *et al.*, 2007). Also, Arrow *et al.* (2011) reported that there was 85% loss after 17 years follow-up and Birkeland *et al.* (2000) showed that there was 17% loss to follow-up after 4 years. Clearly the current study had a much shorter time scale but still had a high dropout rate.

Ethics and R & D approval:

Unfortunately there were significant delays in the ethics process as detailed in Table 72. This delayed the recruitment start date and limited the number of patients who could be recruited. The process took in excess of 6 months from when the completed documentation was first submitted to the point that approval was granted.

Date	The process
April 2013	Approved by clinical director (Dr. Darbar). Submitted to R and D at UCLH.
July 2013	Approved by R and D after delays in the approval process, despite submitting all relevant information.
Late July 2013	Booked through IRAS and advised that it should go to East of England Proportionate Committee.
Early August 2013	East of England Committee rejected the study as it included children and said it should go to a full committee. Booked for 9th September 2013 at Chelsea Ethics Committee
9 th September 2013	Attended ethics meeting and answered questions as asked. The committee advised that we would have an answer in 10 days.
23 rd September 2013	Emailed to ask if there was any progress. Advised there was a delay with the minutes of the meeting.
30 th September 2013	Emailed again - no response.
4 th October 2013	Telephoned and asked about the situation - told there were still delays with the minutes, but we should have an answer within a week.
8 th October 2013	The ethics committee sent the decision letter and on the same day we replied regarding their enquiries.
22 nd October 2013	No response - emailed to ask if they could advise when we would have a response. Also, highlighted the breach in IRAS guidelines due to delays to date.
28 th October 2013	No response - emailed and telephoned again and received a response later that day. Given a favourable ethics opinion.

Table 72: Ethical approval process for this longitudinal clinical study

Choice and distribution of the questionnaires

The questionnaires were selected to explore social impacts and were chosen because they were focused and relevant to the subject area and had been used in orthodontics before in a small number of studies (Mandall *et al.*, 1999; Read, 2013).

All of the questionnaires were collected in a record booklet and it was in a clearly structured self-completion format that was simple and easy to follow. The majority of the participants from the treatment group (98%) and all of the participants from the control group completed the questionnaire in the orthodontic department.

Participants were encouraged to complete the questionnaire in the department for several reasons. Firstly, the Ethics Committee recommended this approach in case participants were distressed by any element of the questionnaires and required subsequent support, albeit this did not happen for any patients. Furthermore, in-person administration helped to develop a rapport with participants and it permitted the researcher to clarify questions and check answers, as well as increasing the completion rate (Edwards, 2010).

Despite the questionnaire being relatively quick and simple, there were 5 patients in the treatment group and 7 patients in the control group who refused to participate in the study. The main reason for refusal was that the patients or parents did not have enough time to be involved.

Recruitment of the participants

Participants between the ages of 10 and 14 years were recruited in order to obtain a representative sample for this research. This is the age when the majority of functional appliance treatment is undertaken in the UK and the different questionnaires in the record booklet were all appropriate and were developed for use with an adolescent population. It should, however, be noted that because the age range of the patients recruited was limited to 10-14 years old, then all conclusions drawn are restricted to that age range.

It is also important to note that, on average, the treatment group patients were significantly older than the control group patients and, whilst this was unavoidable with the study design, it is a limitation of the study. However, it must also be noted that age did not have a significant effect in any of the regression analyses for the different questionnaires.

The demographic distribution in this sample was similar between the orthodontically treated and control groups. However, there were more females than males in both groups. This was similar to other studies which showed that females are more likely to seek orthodontic treatment and this may relate to greater aesthetic concerns than in males (Burden, 1995; O'Brien *et al.*, 1996; Badran and Al-Khateeb, 2013).

Different types of malocclusion might be associated with different social impacts, so it was thought important to include a group of adolescent orthodontic patients with a

homogenous malocclusion (Class II Division 1) for the treatment group and to investigate the social impacts before and after removable functional appliance treatment.

In contrast, the control group included patients with any type of malocclusion. It must be noted that there would have been some Class II division 1 patients in the control group but the group represented the whole spectrum of malocclusions. As explained earlier this group was not an ideal control group but there was no alternative solution. It would not have been ethically appropriate to withhold treatment for anybody who was ready to commence treatment. It could also perhaps be argued that the control group should not have included Class II division 1 patients to allow comparison with all other malocclusions excluding Class II division 1, however this would have made it extremely difficult to recruit the required sample size. This could potentially be considered for future research in this area though.

Recruitment in the control group was one of the greatest challenges for this research and there were several reasons for this. Many patients were ready to commence orthodontic treatment and it was unethical to postpone their treatment for the purpose of this research. Furthermore, some patients were booked for review at less than 6 months or more than 1 year so could not be recruited. Some patients also left the department before the researcher (HMA) could recruit them because it was not possible for the researcher to be present at all new patient clinics. Additionally, some patients were not accompanied by their parent or legal guardian, so had to be excluded as consent could not be obtained.

Limitations of the study

In the UK, Class II division 1 malocclusion affects approximately a quarter of 12 year old children (Thiruvengkatachari *et al.*, 2015). Additionally, 99% of orthodontists use functional appliances to treat patients with this problem (Chadwick *et al.*, 1998). Although there is very little data available regarding the number of Class II Division 1 patients treated with functional appliances in the UK at any one time, a relatively high proportion of referrals to orthodontic departments are Class II/1, albeit not all will be treated with functional appliances. Recent personal communication with one specialist orthodontic practice referring to the Eastman Dental Hospital recently estimated that approximately 5% of their patients have functional appliances, but

this is likely to be considerably higher in the hospital service due to the severity of patients accepted for treatment. However, it must be acknowledged that Class II division 1 patients cannot necessarily be considered “typical” of all orthodontic patients and any conclusions reached in this study should be considered with that in mind.

It is important to note that recruitment of the participants was undertaken from only one department: the Orthodontic Department at the Eastman Dental Hospital, UCLH Foundation Trust. It was not possible to undertake the study in more than one department and this may therefore affect the generalisability of the results of the study.

The socio-economic status of the patients was not reported in this study and this potentially has limitations because how an individual is socially affected or how they respond in social situations may be affected, directly or indirectly, by socio-economic status. A decision was made not to include this variable as there are limitations to the methods which can be utilized. One method often used is postcode but London is relatively unique in frequently having areas of high and low socioeconomic status within a similar postcode and this limits the usefulness of the data collected.

It was also decided not to include ethnicity, as previous similar studies undertaken in the department have found no differences in relation to ethnicity. Large sample sizes are required to fully investigate this variable because patients of many different ethnicities are treated at the Eastman Dental Hospital. Failure to recruit such sample sizes has resulted in only being able to categorize participants as “Caucasian” and “non-Caucasian”, which assumes that all non-Caucasians will behave in the same way and this is unlikely to be the case.

Furthermore, a high loss to follow up was clearly a limitation, as was the significant age difference between the treatment and control groups; the treatment group was older, on average, than the control group.

3.4.2 Discussion of Results

A comparison of those who completed the study and those who did not complete the study was performed. If those participants who completed the study differed

from those who did not, then this may have resulted in the final cohort not being representative of the original target population. Therefore, the age, gender, T1 questionnaire scores and self-perceived IOTN-AC of those who completed the study were compared with those who did not (Tables 43 to 51). There were no significant differences, so those who completed the study were not significantly different from those who were not able to complete for these variables.

It appeared that there was a tendency for a higher dropout from the treatment group than the control group (Table 43), although this was not statistically significant. It should also be noted that failure to complete the study did not equate to failure to complete treatment, as some of the treatment group were still undergoing treatment at the time that data collection for the study was stopped. The finding regarding loss to follow-up was similar to the O'Brien *et al.* (2003; 2009) trial which showed that there were more patients lost from the treatment group compared with the control group at the end of their Class II Division 1 study. O'Brien *et al.* suggested several explanations for this finding including that the patients might be satisfied with the treatment results that they had achieved even if treatment was not technically completed, they may have been less bothered about their teeth or did not have such a severe problem and decided that treatment was not justified with their level of concern. In the current study, there was no significant differences in self-perceived IOTN-AC between those who completed and those who did not complete the study.

Questionnaire findings:

The most important finding of this study was that, based on the questionnaires used, there were no statistically significant social benefits shown by the treatment group patients following functional appliance treatment, when the scores were compared with the control group.

Additionally, there were no significant differences in social impacts between a homogenous cohort of Class II Division 1 and a cohort of patients with a variety of malocclusion types; therefore having a Class II Division 1 malocclusion does not appear to result in greater social impacts than other malocclusions. The effect of self-perceived dentofacial aesthetics (measured using IOTN-AC) was significant for OASIS and MSCS at T1 but not for SAS-A. These findings will be discussed in further detail in subsequent sections.

Although the IOTN-AC data was collected it was not utilised as had been anticipated, this was based on statistical advice advising against combining the OASIS questionnaire scores with the IOTN-AC classification. However, an interesting finding regarding the IOTN-AC was that both treatment and control groups showed a tendency for lower scores at T2 than at T1, which may be related to maturation, with patients becoming less concerned about their teeth. However it would be a relatively short period in which to show these maturational effects. Patients may also have felt better about their dentition because they had either already started orthodontic treatment or knew that they would do so in the near future.

It is important to consider the use of the IOTN-AC as a measure of self-perceived aesthetics. A number of participants highlighted that they could not find a picture which they felt was similar to their own dental appearance (for example, patients with spacing) and experienced difficulty selecting an appropriate image. The researcher offered some help by offering to provide patients with a mirror or suggesting that they looked for similar dental features to their own but this was not always successful. Other studies have discussed similar limitations of the IOTN-AC, including the fact that it assesses the aesthetic aspects of malocclusion only from an anterior view (Bhagyalakshmi *et al.*, 2015), and does not take into account certain dental anomalies (Jawad *et al.*, 2015). This means there are some limitations to using the IOTN-AC as a measure to assess self-perceived aesthetics but it does have other significant benefits and is widely used both clinically and in orthodontic research.

- **The Oral Aesthetic Subjective Impact Scale (Tables 52 to 54 and 63 to 65)**

Relatively few studies have used the Oral Aesthetic Subjective Impact Scale and the majority of studies that have used it were cross-sectional. Therefore, it is difficult to compare this longitudinal study with previous studies. It is interesting that, despite the fact that OASIS was developed for use with adolescents, a number of studies have used it with adult populations (Bernabé *et al.*, 2006; Marques *et al.*, 2009). It is also important to note that previous studies have included the IOTN-AC score as part of the OASIS score and the current study did not do this as explained.

Treatment effects (using T1 and T2 data):

When the T1-T2 differences in scores were analysed, there was no statistically significant difference between the treatment and control groups ($p=0.051$), albeit the p -value was close to significance. In the multivariable regression, the control group had a higher OASIS score than the treatment group at T2 (by 2.467 points), having accounted for all other variables, which suggests more concern regarding dental appearance but this did not reach significance. The only significant variable affecting the OASIS T2 score was the score at T1 and that was not surprising. There was therefore no significant difference in OASIS scores at T2 between the treatment and control groups.

Regarding treatment effect, the findings of the current study were similar to the Mandall *et al.* (1999) cross-sectional study including 434 school children in Manchester. The authors found that OASIS scores were similar between treated and untreated children although untreated children who wanted to undergo orthodontic treatment had higher IOTN-AC and OASIS scores.

Malocclusion effects (T1 data only):

When studying the T1 scores for the whole cohort of patients ($n=114$), again group did not have a significant effect and there was no difference between the Class II division 1 treatment group patients and the control group. The IOTN-AC score was the only significant variable, with patients who selected IOTN-AC 6-10 showing more dental concern than the IOTN-AC 1-5 group and this finding was statistically significant ($p=0.003$ in the multivariable analysis). This finding suggests that OASIS is sensitive to severity of malocclusion and this provides an element of validity to the questionnaire.

Badran (2010) investigated the effects of malocclusion and self-perceived dental aesthetics on self-esteem with a sample of 410 students (aged 14-16 years). The participants completed the Global Negative Self-Evaluation scale and the IOTN-AC. The authors found that those students with greater self-perceived need for treatment had more negative self-evaluation of their own dental aesthetics and this finding is similar to that found in the current study. The authors also noted that students who had orthodontic treatment showed higher self-esteem scores than others who had not undergone treatment.

- **Multidimensional Self-Concept Scale (Tables 55 to 59 and 66 to 68)**
-

In this study, only the social domain of the MSCS was used. There are clearly limitations to following this approach, however it was felt to be more appropriate than including a large number of irrelevant questions.

It has been suggested that self-concept is the result of self-impressions and personal evaluations of one's self-adequacy. It is multidimensional in nature and includes self-efficacy (i.e. one's perceived ability to achieve goals through one's own efforts), self-evaluation of intelligence, strengths and weaknesses, self-esteem, and self-perceptions of physical appearance (i.e. body image). Orthodontic treatment, which often produces positive changes in facial appearance, has been assumed to improve self-concept (Klima *et al.*, 1979) but there remains little evidence to suggest that this is definitely the case.

Treatment effects (T1 and T2 data):

In the multivariable regression, there was no significant difference in self-concept scores at T2 between the two groups, when all other variables had been accounted for. The only significant finding was for the T1 MSCS score. This applied regardless of whether the raw scores or standardised data were used.

A review of the literature provides little evidence to suggest that global self-concept is enhanced by orthodontic treatment in adolescents or adults, although no studies have looked specifically at the social aspects. Adult patients undergoing fixed appliance orthodontic treatment, showed no significant differences in self-concept when pre-treatment scores were compared with those 6 months into treatment or 1 to 4 weeks after debond (Varela and Garcia-Camba, 1995). Similarly, a study of orthodontic patients 15 months after the start of treatment and 1 year after the completion of active treatment indicated that self-concept was comparable with that of a group who had received no treatment (Albino, 1990; Dann *et al.*, 1995). A further study found that self-concept was not significantly different in those patients who presented for treatment and those who had completed treatment (Klima *et al.*, 1979; O'Regan *et al.*, 1991).

In agreement with the current results, three RCTs which investigated the impact of malocclusion and orthodontic treatment on self-concept also found little change in self-concept. These studies all measured global self-concept using the Piers Harris Self-Concept Scale, so the differences between instruments must be considered when drawing conclusions. The current study chose to use a different scale because the Piers-Harris scale does not focus on social aspects and it was therefore felt that it did not address the research question sufficiently well. Dann *et al.* (1995) investigated changes in self-concept of 208 patients (aged 7 to 15 years) before and after treatment for Class II malocclusion with an activator and showed a slight increase in self-concept scores, but the changes after orthodontic treatment were not significant. The authors suggested that children with Class II malocclusions do not generally present for treatment with low self-concept and, on average, self-concept does not improve during the brief period of early orthodontic treatment.

Another trial by O'Brien *et al.* (2003) examined psychosocial benefits from early orthodontic treatment in Class II Division 1 patients using a Twin-block appliance. The results showed significant improvements in self-concept and self-esteem after an early phase of Twin-block appliance therapy compared with the control group. However, the same study was continued until the control group had completed treatment and there was no significant difference in self-esteem or self-concept between the early treatment and the adolescent treatment groups at T3 (O'Brien *et al.*, 2009). It is important to note, however, that the self-concept scores increased for both groups at T3, but there was no control/untreated group at that stage, so it is difficult to interpret whether this increase was due to orthodontic treatment or due to psychological maturation of participants.

The effect of orthodontic treatment for Class III patients under 10 years was evaluated by Mandall *et al.* (2010; 2012) but, after 3 year follow-up, there was no significant impact on self-concept as a result of early treatment with protraction headgear (Mandall *et al.*, 2012).

So, in agreement with the current findings, the above mentioned studies suggested that self-concept undergoes little change over the course of orthodontic treatment and remained relatively stable after active treatment was completed.

Previous studies have shown that orthodontic patients generally appear to be comparable with the general population with regard to self-concept before orthodontic treatment, and therefore self-concept scores may be less likely to show significant changes following treatment. It is also possible that orthodontic treatment may not result in sufficiently large changes in dentofacial appearance which are then able to affect self-concept. Studies also often assess self-concept very soon after completion of treatment and it may be that any benefits of treatment require time to become evident. Overall though, it appears that improvements in dental appearance following orthodontic treatment do not translate into changes in self-concept based on the studies which have been undertaken to date.

Maturation may also affect the way in which adolescents respond to treatment. It has been suggested that self-image decreases from early to mid-adolescence and then increases to previous levels during the teenage years. Moreover, maturation may impact on social interaction patterns, particularly with members of the opposite sex (Simmons *et al.*, 1973). It is thus difficult to establish which effects are due to treatment and which are due to maturation. One study that compared patients who received orthodontic treatment with an untreated control group found that self-esteem, social goals, and social competency significantly improved over time for both groups (Albino *et al.*, 1994). Other authors have cautioned that psycho-social changes after treatment may be influenced by maturation (Brown and Moerenhout, 1991; Varela and Garcia-Camba, 1995; Tung and Kiyak, 1998). Therefore, patients may report feeling better about their appearance and have more positive levels of self-concept and self-esteem regardless of the actual treatment. This could affect both treatment and control groups which complicates research of this type.

Malocclusion effects (T1 data only):

When studying the effect of malocclusion on self-concept scores at T1, Class II division 1 patients did not show significantly different self-concept to the control group. There was a significant finding for IOTN-AC, with those patients with IOTN-AC 6-10 showing less positive self-concept than the IOTN-AC 1-5 group and this finding was statistically significant in both the univariable and multivariable analyses. This suggests that the self-perceived severity of the malocclusion significantly affects the social subscale of self-concept when measured using the MSCS.

A number of orthodontists believe, from their clinical experience, that malocclusion may have a negative effect on psycho-social well being and self-concept. However, studies that have investigated self-concept among adolescents with malocclusion have not always shown negative effects (Albino *et al.*, 1994; Tung and Kiyak, 1998; Phillips and Beal, 2009).

The MSCS was used in a cross sectional study by Phillips and Beal (2009) with 59 patients aged 9 to 15 years who completed the questionnaire before they started orthodontic treatment. The authors found that the self-perceived level of dentofacial attractiveness was more strongly related to self-concept than the clinician assessed severity of malocclusion (assessed using PAR). However, the types of malocclusions included were not specified and this might affect their findings (Phillips and Beal, 2009).

It has been suggested that adolescents with malocclusions may develop feelings of self-consciousness and shame about their dental condition or may feel shy in social contexts, and that their self-concept may be affected as a result of these dentofacial problems (Zhang *et al.*, 2006; de Paula Junior *et al.*, 2009). The findings of the current study would lend some support to this theory if the significant finding for the IOTN-AC is considered.

For patients with low self-concept or low self-esteem, the child's own perception of their malocclusion, rather than the clinical assessment, may be the more important contributing factor. Dennington and Korabik (1977) found positive changes on the self-concept scale before treatment and 7 months into treatment. However, they had no controls and no post-treatment data. In Klima *et al.* (1979) found no significant self-concept or body image differences among orthodontic patients. Their study, however, did not control for objectively evaluated dentofacial appearance or for other potential mediating variables.

Therefore, in conclusion, based on the results of the current study, there was no significant difference between the treatment and control groups. The only significant variable was self-perceived IOTN-AC and those who perceived their IOTN-AC to be higher/poorer, reported significantly poorer self-concept.

- **Social Anxiety Scale for Adolescents (Tables 60 to 62 and Tables 69 to 71)**
-

Treatment effects (T1 and T2 data):

In the current study, there was no significant difference in SAS-A scores between the treatment and control groups at T2.

These findings were similar to a cross-sectional study by Read (2013) which evaluated social anxiety in a group of pre-treatment and post-treatment patients and a control group of adolescents recruited from schools. This study also evaluated the relationship between social anxiety and the Index of Orthodontic Treatment Need Aesthetic Component (IOTN-AC) in order to establish whether there was a relationship between self-perceived severity of malocclusion and social anxiety. The results suggested that social anxiety did not differ significantly in the three groups. The pre-orthodontic group had the highest mean social anxiety scores for all subscales, although the differences were small. Gender was however found to influence social anxiety, with females having significantly higher levels of social anxiety and fear of negative evaluation compared with males. The current study found no significant relationship between social anxiety and gender, age or IOTN-AC.

Researchers have studied the effects of orthodontic treatment on social anxiety and psychosocial functioning; however, there is limited data. Most of the studies did not measure the pre-treatment level of anxiety and did not include pre-treatment comparison, so it was not possible to determine whether the effect was due to treatment or due to differences in the sampling of groups (La Greca and Harrison, 2005; Claudino and Traebert, 2013).

Malocclusion effects (T1 only):

None of the variables included in the regression analysis had a significant effect on the SAS-A and there was no significant difference between the Class II division 1 treatment group and the control group.

As discussed earlier, malocclusion may impact on personality and social behaviour and it may be that adolescents with relatively mild forms of dentofacial disfigurement are at greater risk for the development of psychological problems than those with more severe problems. These patients have been said to develop anxiety due to the inconsistent behaviour of others, whereas patients with more severe problems more consistently receive negative reactions so know what to expect (La Greca, 1998; Claudino and Traebert, 2013). It had been hypothesised that patients with Class II division 1 malocclusions are particularly prone to teasing and therefore may have greater levels of social anxiety. However, this was not proven in the current study.

The self-perceived IOTN-AC had a significant effect on both OASIS and the MSCS but not on the SAS-A. This may be because the questionnaire is not sufficiently sensitive to measure the effects of malocclusion and its treatment or it may be that malocclusion, and its treatment, genuinely do not have a significant effect on social anxiety. More research is required to determine if this is the case.

Overall, the association between malocclusion, orthodontic treatment and social anxiety remains unclear. However, this study found no significant effects related to malocclusion or to orthodontic treatment. It has been suggested that patients who experience social stigma related either to their malocclusion or to their orthodontic appliances may compensate by emphasizing other personality characteristics, thus social competency does not become problematic (Kiyak, 2000). Again, this is potentially an area for future research. There are few studies investigating the impact of malocclusion and orthodontic treatment on social anxiety and more studies with longitudinal designs would be useful in this area of research.

3.5 Conclusions

In the present study, based on the questionnaires selected, there was no evidence to reject the null hypothesis:

1. In Class II Division 1 adolescent patients who underwent removable functional appliance treatment there were no significant social benefits as a result of orthodontic treatment when compared with a control group. Functional appliance treatment did not significantly affect subjective oral aesthetic impacts, self-concept or social anxiety.
2. Patients with Class II division 1 malocclusions did not have significantly greater social impacts than a control group of patients presenting with a variety of malocclusions.

3.5.1 Clinical Implications

Psychosocial variables might affect decisions regarding whether to seek orthodontic treatment and optimal clinical practice requires an appreciation of these factors. With this in mind, it is important that the clinician develops an effective relationship with the patient, with open communication to investigate any social effects that the patient may be experiencing and to provide advice on how any such effects may be effectively managed.

Orthodontic treatment may provide social benefits for a group of children who have experienced teasing and negative stereotyping; however this study did not specifically look at this. This is an interesting area of research and the study by Seehra *et al.* (2013) investigating the effects of interceptive orthodontic treatment suggests that this may be the case.

Well-conducted longitudinal studies examining social interactions following orthodontic treatment are limited and further research in this area is encouraged. However, based on the results of the current study, self-concept and social anxiety appear to remain stable following functional appliance treatment in adolescent patients. It is important to acknowledge however that some individuals may be affected and the patient should be considered holistically.

Chapter IV: A qualitative study of the social impacts of malocclusions in adolescent patients

4.1 Introduction

The previous two chapters investigated the social impacts of orthodontic treatment in adolescent patients, through quantitative methodologies. However, it was also felt important to explore the social impacts of malocclusion and a qualitative approach was chosen for this chapter. It is very difficult to fully understand these subjective concepts in quantitative research and a qualitative study was felt to be important to explore social concerns in more depth as a precursor to future work in this area.

4.2 Subjects and methods

4.2.1 Aims and Objectives

To explore the social impacts of malocclusion in adolescent orthodontic patients utilising qualitative methodology.

To carry out a qualitative study using in-depth interviews to investigate the social impacts of malocclusions in adolescent orthodontic patients.

4.2.2 Study design

This was a prospective qualitative study, involving one-to-one in-depth interviews to investigate the social impacts of malocclusions in adolescent patients. As for Chapter II, the focus was specifically on social issues. The interviews were analysed using a framework analysis.

4.2.3 Ethical considerations and Study approval

Study approval

Research and Development (R & D) Department approval was granted from University College Hospitals Foundation Trust London and ethical approval was granted from the Chelsea Research Ethics Committee; a favourable ethical opinion

was obtained on the 24 December 2014 (Appendix 9). This study was a substantial amendment to the prospective longitudinal study (Chapter III) with the aim of further exploring the social impacts of malocclusion.

4.2.4 Inclusion and Exclusion Criteria

Patients were invited to participate in the study if they were attending their orthodontic appointment as a new patient or if they were in the planning stages prior to commencing active treatment. The inclusion and exclusion criteria are given in Table 73.

Participants in the qualitative study	
Inclusion criteria	Exclusion criteria
12 to 16 years (inclusive)	Patients with craniofacial syndromes, such as cleft lip and/or palate
Male or female	Individuals with traumatic or pathological facial conditions
All types of malocclusions	Patients with diagnosed behavioural or psychological disorders (as detailed on the medical history)
Patient and parent willing to participate in the study	Orthognathic patients
Parent or legal guardian and patients agreed to take part and provide consent	

Table 73: The inclusion and exclusion criteria for the qualitative study

4.2.5 In-depth interviews

Interview training and practice interviews

Before commencing the study, the researcher (HMA) attended two courses: an “In-Depth Interviewing” course on 25th and 26th June 2013 and “Analysis of Qualitative Data” on 12th and 13th June 2013 at the National Centre for Social Research (NatCen), an independent social research organisation in London, UK (Certificates provided in Appendix 10).

The in-depth interviewing course was designed to provide the skills and experience to conduct qualitative interviews, the course topics were delivered by taught and practical sessions to understand the essential skills and techniques including: active listening, open questioning, probing and the use of topic guides. The analysis of qualitative data introduced the “Framework approach”, the key stages, analytical processes and interpretation of data. Some of the challenges which might face the interviewer were also highlighted.

Practice interview training was also undertaken with the primary research supervisor (SJC), who is experienced in the field of qualitative research and interviewing. The training included learning how to probe different issues and how to explore relevant issues in a flexible non-leading way. Training also included how to deal with sensitive issues if they arose. Initially, practice interviews were with the primary supervisor acting as the patient, then with colleagues who were given scenarios to act out and with feedback from the primary supervisor and colleagues.

Topic guide development

During this training, a topic guide was developed (Appendix 11). Key questions were chosen through discussions within the research team, reviewing similar topic guides previously developed, and reviewing the literature. However, the interviewer was free to deviate from the guide and ask relevant follow-up questions if needed. This process allowed the topic guide to be updated with new topic areas when they arose during the actual interviews.

4.2.6 Purposive sampling

A common method of sampling in qualitative studies, purposive sampling, was used in this study. Participants were selected to represent key characteristics (gender, age and different types of malocclusions) in order to enable the researcher to explore and understand a broad range of the topics of interest. Interviews were conducted until no new themes arose.

4.2.7 Consent process and Confidentiality

Adolescent patients accepted for orthodontic treatment who fulfilled the inclusion criteria (Table 73) were initially spoken to by their own clinician. If they showed interest in being involved in this study, they were then introduced to the researcher (HMA) who explained the study in detail and gave the participant information leaflets (PILs). The participant information leaflets were created in 2 forms, one for patients and the other for parents. The content of the information leaflets was the same but the wording was aimed at a younger reader in the patient information leaflets.

The patient and parent were then given adequate time to decide if they wished to be included in the study. If they made a decision to be included, the patient signed an assent form and the parent or legal guardian a consent form (Appendix 12).

All patients and parents were assured of confidentiality. They were reassured that nobody would have access to the interview recordings other than the research team and their name would not be linked to anything said in the interviews. Furthermore, the interviews were conducted in a private setting within the department and all audio recordings deleted immediately after transcription. They were also reminded that participation in, or withdrawal from, the study would not affect their treatment in any way.

4.2.8 Participant interviews

Interviews were conducted face-to-face by the researcher (HMA) in a private setting within the department. The research supervisor (SJC) observed the first four interviews to ensure that the full range of topics was being explored. The patients

were given the option of being interviewed with, or without, their parent present and all interviews were recorded using a digital recorder. Questions from the topic guide were used to guide the interview and it was stressed to patients that there were no right or wrong answers; the researcher was just interested in their opinions. Interviews were terminated when the patient has no additional information to provide. The interviews ranged from 14 to 23 minutes.

4.2.9 Analysis of the Interviews

There are a number of different approaches to qualitative analysis. However, in this study, data were analyzed using the “framework method” developed and popularised by the National Centre for Social Research (Ritchie and Lewis, 2003). The concept of 3 analytical stages was used: data management, developing a framework and interpreting the data.

Stage 1: Data management

An experienced transcription company called “Typing Works” transcribed all interviews. A written agreement (Appendix 13) was signed between the company and UCLH NHS Foundation Trust to ensure confidential management of all information. Each transcript was coded to ensure confidentiality of the patients and was uploaded to an encrypted site, then deleted from the digital recorder.

When transcripts were returned, they were read several times by two researchers (HMA and SJC) to allow the researchers to familiarize themselves with the data. The researchers read the transcripts line by line, key phrases were highlighted and label “codes” applied using coloured highlighter pens. Coding helps to classify data into themes (Appendix 14).

Stage 2: Developing a framework

In this stage, themes which had been identified and colour coded were then entered into an Excel spreadsheet. These themes were further analysed and subthemes identified (Table 75). One spreadsheet was produced for each theme; the columns represented the subthemes and each row represented one participant. Direct quotes taken from the interview transcripts were entered into the cells, along with the line number from the transcript. Consideration was then given to the themes and

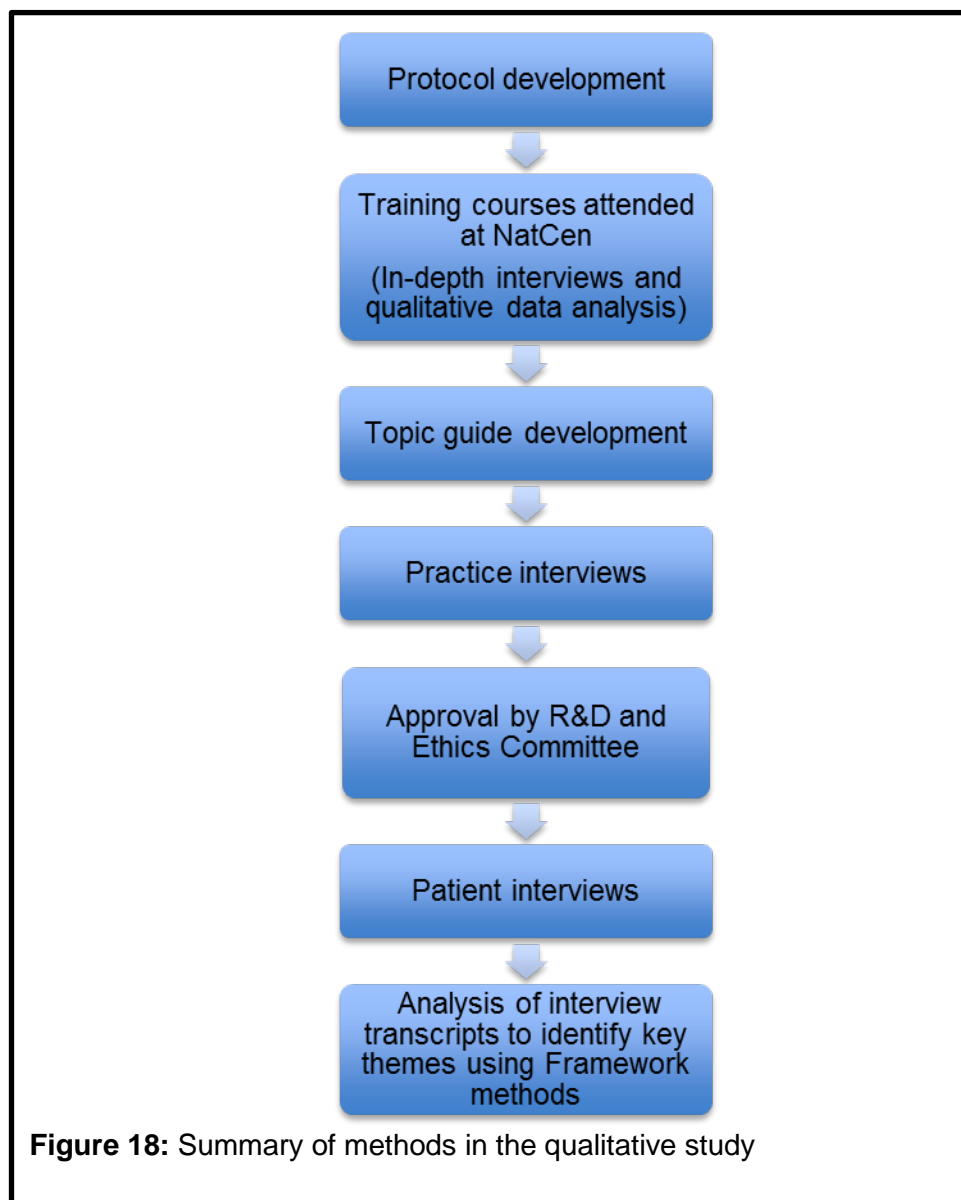
subthemes and amendments made as required.

This iterative process was performed by both researchers (HMA and SJC) and there were changes in the themes and subthemes until the researchers were certain that the analysis included all viewpoints described. The resultant framework allowed easier comparison of interviewee comments for each theme and helped to generate descriptions and further understand the topic under investigation, thus allowing a clear overview of the data.

Stage 3: Interpreting the data

The final stage in the analytic process was interpreting the data, which involved exploring and discussing the participants' results.

4.2.10 Summary of methods



4.3 Results

4.3.1 Demographic of patients

The demographics of the participants are summarised in Table 74. Fifteen patients were invited to participate in the study, however, 3 patients declined to take part therefore data was available for 12 patients.

Of the 12 participants in this study, 9 were females and 3 were males. The ages ranged from 12 to 15 years. The cohort included a range of malocclusions, 2 patients had a Class I incisor relationship, 7 patients had a Class II Division 1, 2 had a Class II Division 2 and 1 patient had a Class III incisor relationship. Of the twelve patients, one also had an impacted canine and one had hypodontia.

Patient identifier	Age	Gender
P1	13	F
P2	13	F
P3	13	M
P4	15	F
P5	14	F
P6	14	F
P7	14	M
P8	13	F
P9	14	F
P10	13	F
P11	12	F
P12	13	M

Table 74: Participant demographics for the qualitative study

4.3.2 Analysis of the interviews

Main themes and subthemes

Three main themes were identified which related to the social impacts of malocclusion in adolescent patients:

1. Interpersonal relations
2. Feelings regarding facial images
3. Teasing

Further analysis of the main themes resulted in several subthemes and these are shown in Table 75. Each theme, and its subthemes, will be discussed in turn, with quotes from the interviews used. These quotes will be associated with the participant ID number (e.g. P1 indicates Participant 1), gender, age and the line numbers from the transcript. Explanatory comments have been provided where necessary.

Social impacts of malocclusion in adolescents patients			
Main Themes	Interpersonal relations	Feelings regarding facial images	Teasing
Subthemes	Smiling and showing teeth	Photographs	Types of teasing
	Interacting with people they know	Videos	Perpetrators: family, school, others
	Meeting new people	Social media (e.g. Facebook and Instagram)	Media influence
	Effects on school activities	Facial appearance and mirrors	
	Effects on out of school activities		

Table 75: The main themes and associated subthemes, resulting from analysis of the interviews

Theme 1: Interpersonal relations

Smiling and showing teeth

Concerns about dental appearance affected social behaviour in some participants. Several participants reported that they closed their mouth when they smiled, especially when while meeting people, to ensure that their teeth could not be seen. Furthermore, some described their emotional feelings regarding always having to hide their teeth when smiling. Some reported that this annoyed them and others reported feeling self-conscious and having to remind themselves to close their mouth when smiling. However, one participant said that this was not an issue which worried them at all so not all participants were equally affected.

"It's most of the time, just sort of reminding myself to like close my mouth when meeting people" (P1, F, 13yrs, 255).

"Quite annoying, because it feels like you always have to pay attention to if they're [teeth] showing or not and you just can't, you can't be like yourself completely, you just have to be more careful what you're doing, it's just annoying I guess" (P6, F, 14yrs, 134).

"Sometimes when I'm smiling or something, I would like to see myself without a gap because it looks different, it looks weird compared to other people's teeth" (P7, M, 14 yrs, 161).

"If I have straight teeth, I'll feel more confident and I'll feel like I can smile whenever I like 'cos I have nothing to be self-conscious about, you know" (P6, F, 14 yrs, 315).

Interacting with people they know

Some participants talked about concerns when interacting with people they already know and a number of participants discussed being more concerned with classmates than with friends or family. Some participants stated that they felt friends and family liked them "for who they are" and did not comment about dental issues, therefore this was not something they were concerned about.

"I am not really worried with my friends, but a little bit more with my classmates" (P1, F, 13 yrs. 155).

"I actually don't worry, like my friends are nice so they don't really care about how your teeth look like or not" (P2, F, 13yrs, 149).

However, some participants did worry when meeting friends and one participant mentioned that a conversation with a friend about her teeth bothered her.

"Like sometimes with friends, I prefer just to smile and not like grin, or show my teeth because then people will see. So like at times when I want to grin maybe I'll have decided not to 'cos I don't want to show them my teeth, so I just smile at something like that" (P6, F, 14 yrs, 116).

"I had a conversation about teeth with my friend once but that was after I went to the dentist and she was like, "I have perfect teeth, ha ha," and I was a bit annoyed" (P4, F, 15 yrs, 251).

Meeting new people

The third subtheme related to meeting new people. The majority of participants talked about meeting new people, although this did not seem to be a major concern. Participants often felt that new acquaintances would not comment on their teeth so did not feel too worried under these circumstances.

"It's not too bad when you're meeting new people because like you won't really comment if you're just meeting someone, you're not going to comment on how they look so it's fine" (P1, F, 13 yrs, 177).

"I probably wouldn't think about my teeth just 'cos I was meeting new people" (P4, F, 15 yrs, 351).

"I mean we talk to new customers like all the time and I've never even thought about my teeth, I mean I'm too busy trying to get stuff done to even consider, and also when you're working at a stables [*the participant worked in a stables at weekends*] your teeth aren't really like the worst thing about your appearance, so not really top of my priority list" (P5, F, 14 yrs, 277).

In contrast, one participant did discuss how she felt uncomfortable when meeting new people and was hopeful that orthodontic treatment would help her feel more confident in such situations.

"Like I have the same feeling when meeting new people, if not more uncomfortable with my teeth than when I am meeting friends" (P6, F, 14 yrs, 199).

Effects on school activities

A number of participants discussed how they felt when involved in school activities, but, in general, interviewees felt relatively comfortable in a school situation.

"It does not stop me from doing any activities with friends or any colleagues" (P2, F, 13yrs, 160).

"So my teeth won't matter to like my activities and stuff" (P8,, F, 13 yrs, 286).

"Like when I'm running it doesn't matter if my teeth is forwards or not" (P8, F, 13 yrs, 291).

Effects on out of school activities

When participants were asked about how they felt when they were involved in out of school activities, a variety of responses were recorded. Several participants said that they felt more confident during out of school activities than they did at school; interestingly this was despite many participants saying there were no major effects at school.

"I'm like more confident when I go to dance, yeah" (P1, F, 13 yrs, 223).

"Yeah, I do, I feel more confident in outside activities as well" (P12, M, 13 yrs, 187).

"I wouldn't say that I've ever felt self-conscious about it there" (P5, F, 14 yrs, 272).

One participant discussed why he felt more confident in out of school activities. He said that people from his school knew his strengths and weaknesses and sometimes used that as a way of upsetting him but this happened less in out of school situations.

"I do some stuff outside of school but no one outside of school really says anything about my teeth. I don't think they even notice and I think because in my school like they know my strengths and weaknesses, like they know that I'm not particularly good at some stuff but I'm particularly good at other stuff" (P12, M, 13 yrs, 160,196).

Theme 2: Feelings regarding facial images

This was a major theme and all participants discussed aspects of this theme at some point during their interview.

Photographs

When participants were asked about situations that made them self-conscious about their teeth, the majority discussed negative feelings when having photographs taken. Different terms were used by participants to express these feelings, especially if they were specifically asked to smile. These terms included: self-conscious, annoying and uncomfortable.

"It's just a bit self-conscious, like I don't mind that much, it's just, you know, you want to look nice and I feel like my teeth stop that sometimes so yeah" (P1, F, 13 yrs, 367).

"I notice I have a missing tooth, sometimes I'm like that's annoying and they can delete the photo 'cos it looks stupid. Its kind of a weird photo" (P4, F, 15 yrs, 174).

"When I just joined Scouts then I was quite uncomfortable, when we had to take photos and then we had to be smiling" (P6, F, 14 yrs, 221).

Several participants described keeping their mouth closed in photographs to hide their teeth when they smiled. Participants talked about how this made them sad or unhappy.

"Normally when I smile, I don't show my teeth, in pictures and things. It makes you more of a straight-faced person. It makes you look like you're not happy or something in the picture because everyone's like smiling and you're like this. It feels normal but I'd like to see myself smiling with an open mouth" (P7, M, 14 yrs, 208).

"When I am looking at pictures, I wish that my teeth were like straight so there was no gap. Because they would look nicer that way. I think maybe it'll just like help you smile more and be happy about them" (P9, F, 14 yrs, 270).

"I would just like close my mouth and smile. It's quite sad because I can't smile like other people, they can smile and show their teeth, they don't have anything wrong with it" (P10, F, 13 yrs, 480).

"On pictures I don't like showing my teeth" (P2, F, 13yrs, 193).

One patient described how he rarely smiled in photographs but said if it was a family photograph he was more likely to smile.

“Well maybe sometimes I will smile on picture but not a lot. Obviously if it’s like a family photo then I might smile” (P3, M, 13 yrs, 359 and 368).

Although the majority of participants discussed being worried about having photographs taken, a small number of respondents were less concerned. One participant said that he did not worry so much about photographs as he would not show them to anybody anyway; this was in relation to photographs taken at school rather than general aspects of having pictures taken though.

“I have no problem smiling while people take photos of me” (P8, F, 13, yrs, 256).

“I don’t mind taking photos, I mean even if it’s me smiling, I don’t smile that much really. In general I probably smile a lot more than in photos, but in photos I don’t really mind because it’s not like I’m going to show it to people, I’m just going to like put it in my bag, bring it home and it stays at home” (P12, M, 13yrs, 259).

Videos

One participant described how she felt “bad” seeing herself and her teeth in videos, she said that she felt self-conscious and that she would ask her friends to delete a video if it showed her teeth.

“I’m self-conscious when I smile sometimes but that’s mainly it, but I’ll see a video of myself and be like oh god, so I’ll try not to do whatever I was doing. In photos or like videos of myself, if I see them and my teeth are like in them, then I feel bad about it, so yeah. Get my friends to delete them, yeah” (P1, F, 13yrs, 187, 362).

Social media (Facebook and Instagram)

Several participants described how they felt if someone posted a photograph of them which they did not like on social media, such as on Facebook or Instagram. One participant reported not being too worried and another described how, he would explain the reason for his dental problem, if anyone commented negatively on such images. However, a number of interviewees report significant concerns. These responses included asking their friends or others to delete the photograph if they did not like it and feeling “sad” or “not too happy” if their friend chose not to delete the image. One participant also said she felt sad because some people made assumptions about her because of her dental appearance and she felt that she was judged negatively.

“If someone posts my photo on Facebook, it’s like, okay, doesn’t really matter, yeah” (P5, F, 14 yrs, 199).

“If any one of my friend tagged me on Facebook and I did not like the photo. I wouldn’t mind but I wouldn’t be too happy” (P7, M, 14 yrs, 274).

“I’d probably be like “Oh are you going to take that (the photo) down?” And if they’re like “No, no, no, I don’t want to take it down”, I’m like “Okay, okay”. But if I see any comments about my teeth, like I would ask them “Can you take it down?” Hopefully they’ll understand, like most of my friends would understand now so hopefully they would like say “Okay, yeah, if anyone makes a comment about your teeth, I’ll just take it down”, so yeah” (P12, m, 13 yrs, 272, 286).

“When people ask me to smile when taking a photo, I smile with my mouth closed and that makes me feel sad. Because then people will like put nasty comments or judge me” (P10, F, 13 yrs, 505).

A small number of participants used Instagram and discussed how they reacted to people posting photographs of them. Some participants described not being too worried as they felt people did not generally comment about people’s teeth on Instagram. Others discussed asking friends to delete images they were not happy with and which showed their teeth and one participant said she would take “revenge” if somebody posted a photograph she did not like and refused to delete it.

“...When my friends post pictures on Instagram and tag me, it’s not like actually my face, it’s like other friends and so, but if they do I would just tell them to delete it because it’s personal and... Maybe it looks better when I think about it later and maybe I won’t have to worry about like people posting pictures of me on Instagram” (P8, F, 13 yrs, 355, 396).

“If my friend was going to take a picture of me and her or in a group I’d always say “can I see the picture, see if it’s alright?” So I don’t think that would be a problem and even if I didn’t like the picture I think nobody would really say anything on Instagram” (P11, F, 12yrs, 386).

“I would take revenge about it. If they didn’t delete it then I would just take a picture of them which they don’t like... like they look ugly and then I’d put it on Instagram and everyone can see” (P2, F, 13yrs, 202 and 212).

Facial appearance and mirrors

A range of emotions was described by participants when they discussed looking in mirrors. A number of the interviewees mentioned that were aware that they were “different” in comparison with other people and that looking in mirrors highlighted that. Another participant said that she felt insecure when she saw her teeth in the mirror.

“Just looking in the mirror, and my teeth and yeah just saw it. This makes me feel like I’m not like everybody else ‘cos most people’s teeth look nice and straight, but my teeth are not, so it just makes me feel a bit out of the ordinary I guess, yeah” (P6, F, 14 yrs, 106).

“Just from like looking in pictures and the mirror and stuff. I wish that it [*my teeth*] was like straight so there was no gap. Because they would look nicer that way. I think maybe it’ll just like help you smile more and be happy about them” (P9. F, 14 yrs, 92, 208, 212, 270).

“I feel insecure when I see my teeth in a mirror” (P10, F, 13 yrs, 141).

The duration of the feelings precipitated by looking in mirrors was described by one participant as being temporary and did not affect her after she had stopped looking at her image.

"I don't think I really think about it [*my teeth*] that much after looking in the mirror" (P9, F, 14 yrs, 195).

Theme 3: Teasing

Types

Several participants discussed being teased but the teasing did not always relate to dental problems. The majority of participants discussed teasing at some stage in their lives and recalled a number of negative situations, including people making unpleasant comments about their teeth. However, none of the respondents reported that they were physically bullied because of the appearance of their teeth.

"I mean like sometimes at school I get comments about it [*my teeth*], like, you know, buck teeth and stuff which isn't very nice, but yeah, it's not that bad, it's sort of normal in schools. I think. It's okay 'cos like people in schools are just mean, that's like how it works, 'cos you're always going to get comments about things so you just deal with it" (P1, F, 13 yrs, 108, 282).

"I didn't really start to realise that they were trying to make fun of my gap [*in the teeth*] until I got a bit older but it was quite upsetting because they were making fun of it, I wasn't really a very aggressive child so I couldn't really say anything....." (P11, F, 12yrs, 18).

"I think this can happen to anyone and it just happened to me. It was just unfortunate and I have been made fun of because of my teeth but I've just let it pass really because I know like if I... they wouldn't like it to happen if someone said that to them, if they had my teeth" (P12, M, 13 yrs, 42).

The reaction to teasing depended on the individual participants and some appeared to demonstrate more effective coping skills than others. They described different strategies such as ignoring the comments, trying to hide their teeth, trying to explain the problem and seeking family support. In contrast, others were clearly upset by the teasing they experienced.

A small number of participants felt that these comments were not necessarily negative and considered it a joke. However, others felt that even if it was a joke, the comments were still hurtful.

"I'd try and put my head down and close my mouth when I talk and I would like to be able to talk loudly but I didn't like open my mouth a lot because I didn't really like people to see my gap" (P11, F, 12 yrs, 137).

"When someone teases me because of my teeth, I remember that when I get braces and my teeth are straight then I will feel happy" (P10, F, 13 yrs, 216).

"I don't see it as bullying but I see it as sort of jokes and stuff. However, when it's getting too far, you try and stop it or if you see the person being emotional or it's getting to them" (P7, M, 14 yrs, 392 and 401).

"My uncle used to tease me as a joke, but like it was really mean, he thought it was a joke, but I didn't like it" (P2, F, 13 yrs, 353).

Importantly, most participants said that they would not talk to teachers at school about such teasing because they felt teachers did not care or felt that this would make the situation worse if a teacher did try to intervene.

"Well I did tell my parents, but like I told them not to do anything about it because I knew I had to do something by myself. So I knew that telling a teacher would not help even though they say it does help, it doesn't because then they just see that you're weaker and they make fun of you again and again and again. They don't really care about getting in trouble. So I just told them "Okay, cool, I don't really care" (P12, M, 13 yrs, 107).

"I did not tell my teachers that some of my classmate made comments because I don't think teachers care that much". (P1, F, 13 yrs, 329).

Not all participants reported teasing due to their teeth. One participant said that this might be because people did not see the gap caused by their missing teeth.

"I mean no-one's ever really commented on my teeth and said, "Oh your teeth are really wonky," or, "You're missing lots of teeth," or anything. In fact when I tell people that I'm missing these two teeth here they still think... like they can't see the gaps so I don't really find my teeth much of a social issue if that makes sense" (P5, F, 14 yrs, 68).

"Most of the time I forget about it so it's not too bad, but it's... I don't know, no-one says bad things about it, it's just kind of annoying" (P4, F, 15 yrs, 92).

"Nobody's made any comments about my teeth, I just don't like them myself, so yeah" (P6, F, 14 yrs, 156).

When the participants were asked about how people teased them, this mainly involved calling names, such as "buck teeth" and "horse teeth" or asking questions about their teeth which they knew would cause some distress.

"It's fine, it's just sort of stuff like, your teeth stick out, or like buck teeth and stuff, so yeah" (P1, F, 13yrs, 119).

"He just says oh you've got a buck tooth or horse tooth like if he gets angry at me" (P10, F, 13 yrs, 193).

"They were just asking me questions, to make fun of me like "What's wrong with your teeth?" or "Why are your teeth yellow?" and that kind of stuff. Just asking me questions which are a bit stupid even though that they knew the answer, it kind of annoyed me really" (P12, M, 13 yrs, 100).

Perpetrators: family, school, others

The participants reported different people teasing them, including family members (siblings, uncle), classmates and friends. A small number of participants said that family members teased them; one participant said that her uncle teased her as a joke, however, she did not like this and was upset by it.

"My uncle used to tease me as a joke, but like it's really mean, like in a joke way, but I don't like it" (P2, F, 13yrs, 353).

"My younger brothers tease me" (P10, F, 13 yrs 185).

Teasing was usually by people they already knew and the majority of participants who were teased, experienced this at school by their classmates.

"Like people at my school, like classmates and stuff" (P1, F, 13 yrs, 130).

"My classmates were teasing me" (P11, F, 12 yrs, 209).

"Some of my classmates, some were just in my year. None of my friends really did it because they knew that it would just annoy me really" (P12, M, 13 yrs, 117).

Some participants mentioned that they thought teasing was related to gender and it was felt that boys teased each other more than girls. One participant said that boys teased each other about everything, including teeth. Another participant said that they thought the reason that boys teased people more than girls was related to the aggressive nature of boys.

"It's mainly guys, just calling you like everything that's wrong with you" (P1, F, 13 yrs, 288).

"I think it's girls that notice it 'cos guys are used to it and they all do it to each other and girls are nice to each other and then the guys are like, "Oh my god, you're so ugly," so yeah" (P1, F, 13 yrs 294).

"A boy in my class got braces and then he kept putting his hands over his mouth, and then it was like, "Oh come on, show us your braces," and then he was just kind of embarrassed about it" (P4, F, 15yrs, 283).

"Because they [boys] were more aggressive than the girls and I was friendly with near enough all of the girls so I don't think they'd really say anything" (P11, F, 12 yrs, 218).

Other participants discussed that teasing may relate to age as they were teased more when they were younger. One participant described that she was teased when she was younger, however, now that she was in secondary school, people were more conscious of what they said. Another participant said that he started to ignore what people were saying to him in secondary school and this resulted in the teasing stopping. In contrast, other participants noted more teasing in secondary school than in primary school.

"Well I don't really mind my teeth but it's just like I think, in primary school people sort of made fun about my gap a bit more, but now I'm in secondary school and people are a bit more conscious of themselves than they were in primary school, I think everybody's sort of got their own flaws so I don't think that it really bothered me as much because nobody really talks about them as much as they did in primary school" (P11, F, 12 yrs, 69).

"It's just a couple of people in my school, the same year as me, it only happened in the first year of secondary school by new people and in my primary school no one made fun of my teeth because no one really paid attention. But like now I was in secondary school everyone was like, you know, deciding on who is going to be the coolest people and stuff, deciding on their looks, I just happened to be picked out as the person with not normal teeth and I was made fun of but since they found out that I didn't really care they stopped" (P12, M, 13 yrs, 83).

"Other people were teased but like I don't think as bad as me though. Most people know that I was teased but like no one really gets teased by them anymore because we're in the third year now" (P12, M, 13 yrs 316).

Teasing usually occurred in public and one participant described his feelings when he was a witness to a number of teasing situations and said that he would try to stop it if he saw the victim emotionally affected.

"When it's getting too far, you try and stop it or if you see the person being emotional or it's getting to them" (P7, 14 yrs, M, 401).

Media influence

The effect of the media in relation to teasing was discussed by some participants. For example, one interviewee said that people call her names of TV characters, such as Bugs Bunny.

Not all discussions regarding the media related to teasing. Another was worried that people might not like her because of the gap in her teeth and she said that this feeling related to her watching a TV programme with a girl who had the same problem.

“Like, they might call me something from TV shows, there was Bugs Bunny so they’d call me Bugs Bunny teeth. They’d say that somebody had like punched a tooth and me had fallen out and they’d always make a joke about it. I didn’t really start to realise that they were trying to make fun of my gap until I got a bit older but it was quite upsetting because they were making fun of it. I wasn’t really a very aggressive child so I couldn’t really say anything back but...” (P11, F, 12 yrs. 184).

“Oh like if you watch, uh, if you watch this programme “Episodes”, I watched this episode the girl she had a gap in her teeth so she wanted to get braces but her parents said no because they couldn’t afford it and they were in America and then she couldn’t afford it so then she started hurting herself, yeah, that’s what happened” (P10, F, 13 yrs, 298).

4.4 Discussion

4.4.1 Discussion of methodology

Interview training and topic guide development:

In-depth interview training was carried out as the researcher (HMA) had no previous experience of this type of research. The training was undertaken by NatCen experts and then training by the primary research supervisor (SJC) who is experienced in qualitative research methods. This training was essential for the researcher (HMA) to gain the confidence, skills and techniques to conduct the interviews and explore the patients' thoughts regarding how they felt about their teeth in different social situations.

Additionally, practice interviewing with colleagues and the gradual development of the topic guide allowed the researcher (HMA) to gain the necessary experience and skills to conduct the research. This was through a range of scenarios of different situations that may arise during the interviews and how to cope with them. The practice interviews were either observed by the research supervisor or were recorded and listened to subsequently. Feedback was given afterwards and key areas for improvement were highlighted, including probing specific aspects in a non-leading manner, using the appropriate vocabulary for the patient's age and showing empathy in response to the patients' answers.

Concepts related to the research topic were identified through searching the literature. Further discussion with the research team then allowed development of the topic guide, which was used during the practice interviews and this was amended a number of times throughout this process to ensure that it was comprehensive. The guide allowed flexibility to explore new themes in detail and any new topics which arose during the interviews were included in the topic guide to ensure that they were included in future interviews.

Participant recruitment

Twelve patients were interviewed, at which stage there did not appear to be any new themes arising. Qualitative research does not require large numbers of participants in the same way that quantitative research does because the goals of this type of research are different. Quantitative research seeks to generalize the results from a sample to a population; therefore researchers require variation in subjects and a large sample size. In contrast, the goal of qualitative research is to gain an “in-depth-understanding” of specific individuals. Experts in the field state that sample sizes in qualitative studies depend on the research objectives, the type of analysis and practical considerations, such as accessing participants and resources (Baker and Edwards, 2012).

Three patients declined to participate in this study because they did not have enough time to discuss the study and be interviewed. However, this should not affect the study to a great extent because in qualitative studies, the researcher continues interviewing until no new themes arise. This is sometimes called “saturation”, although it has been questioned as to whether true saturation is ever achieved.

Purposive sampling was undertaken in order to capture variations in age, gender, and malocclusion. The patients included in this study ranged from 12 to 15 years of age and this age range reflects the majority of orthodontic patients. Corrective orthodontic treatment using fixed appliances is often commenced around this age, a time when physical appearance is crucial. Of those interviewed, 9 were female and 3 male, this was not the gender distribution originally described in the sampling framework. However, this distribution was accepted due to the time constraints affecting the study. Future studies in this area should potentially focus on gender differences as this may be an interesting aspect to explore.

As discussed in Chapter III, ethnicity may be important when considering social impacts of malocclusion. Ethnicity was not included as part of the purposive sample for a number of reasons but primarily for practical reasons, within the time constraints of this study it would not have been feasible to recruit sufficient patients to have a wide range of ethnicities. The issue of ethnicity and its potential influence on how patients feel about malocclusion/ orthodontic treatment would certainly be of interest in future studies but it is important to note, that some studies have reported

reluctance of patients to take part in qualitative studies where there are ethnic-sensitive aspects to the research (John and Rutledge, 1993; Macneill *et al.*, 2013). This adds to the difficulty of exploring certain variables in research of this type.

Patients who had not yet commenced active orthodontic treatment were recruited for the study. It was important to include participants with different types of malocclusion as they may be associated with different social impacts. The study included Class I, II division 1 and 2, and Class III incisor relationships, as well as canine impaction and hypodontia. Again, future studies could explore the differences between malocclusions, although this was not the focus of the current study.

Participant interviews

Qualitative research is used in health care and social research to answer research questions related to the study of human and social experiences, feelings, motivation and thoughts (Malterud, 2001). Focus groups and in-depth interviews are the most common tools used to collect such information and are effective in letting people talk about their personal feelings and experiences. In the current study, the main reason for using one-to-one interviews was that it was hoped that participants might feel more able to express their feelings than in a focus group where children and adolescents may feel inhibited (Milena *et al.*, 2008). Additionally, from a practical point of view, it was possible to interview patients when they attended for a routine appointment and it was not necessary to arrange another time for the focus group.

All interviews were carried out in a confidential non-clinical setting within the Orthodontic Department, in order to relax the interviewees. Due to ethical requirements patients were asked if they wished to be interviewed with, or without, their parent or guardian present. All of the patients chose to be interviewed alone and this allowed open discussion with the researcher with no potential parental influences on the information they offered.

Analysis of Interviews

Different methods may be used to analyse qualitative data, the most commonly used methods being the framework, content and grounded theory approaches

(Ritchie and Lewis, 2003). The method of analysis used in this study was a framework analysis, as developed by Ritchie and Spencer from the National Centre for Social Research (NatCen) in the UK in the late 1980s (Ritchie and Lewis, 2003). This method is considered a flexible and systematic approach to analyse and explore qualitative data in depth (Gale *et al.*, 2013). However, it is time and labour intensive because it requires transcripts to be read and re-read and then Excel frameworks need to be produced and amended until all opinions have been included in that framework.

In the present study, the analytical process was performed in collaboration with an experienced and senior researcher (SJC) within the field of qualitative research. The researcher (HMA) also attended a course by NatCen which teaches this approach.

4.4.2 Discussion of results

There were three major themes identified in the framework analysis and each of these was also associated with subthemes. Each theme and its subthemes will be discussed accordingly.

Theme 1: Interpersonal relations

The subthemes that arose regarding interpersonal relations were as follows: smiling and showing teeth, interacting with people they know, meeting new people, effects on school activities and effects on out of school activities.

Smiling and showing teeth

A number of participants described how they closed their mouth when they smiled when meeting people to ensure that their teeth were not showing. Furthermore, some described their emotional feelings regarding always having to hide their teeth when smiling. Their feelings included being annoyed and also self-consciousness. Interestingly, these issues did not affect all interviewees equally and a small number of participants said this was not an issue which worried them.

The results of the current study confirm the view that adolescents are concerned about dental appearance (Klages *et al.*, 2004) and this concern did appear to affect their social behaviour. The interviewees believed that their teeth and smile were

important aspects when evaluating people and when being assessed themselves. Based on such beliefs, some participants thought that they were being judged by others based on the appearance of their teeth and smile.

These findings were similar to a study by Taghavi Bayat *et al.* (2013) which found that for young adolescents, it was important to feel socially comfortable without focusing on their teeth and feeling the need to hide them. This study involved 12 Swedish adolescents (aged 13-14 years) who participated in focus groups and they concluded that adolescents with malocclusions are often reminded of their dental problem and this can lead to avoidance strategies, such as hiding their teeth and striving for a “cure” to minimize the negative feelings associated with their teeth (Taghavi Bayat *et al.*, 2013). In another study by Josefsson *et al.* (2010), 13 participants were interviewed to study the impact of dental aesthetics on their everyday life. Although they were older patients than in the current study (aged 19-20 years), they also reported avoiding showing their teeth.

Different types of malocclusions might have a different impact on smiling. In a questionnaire based study by Moura *et al.* (2013), the authors studied the negative self-perception of smiles because of malocclusion in Brazilian adolescents (aged 12 to 16 years). They found that crowding (2mm or more), spacing or an anterior open bite led to more negative self-perceptions of their smile. They also reported increased dissatisfaction with smiles in association with an increased severity of malocclusion. A cross-sectional study by Traebert and Peres (2007) also reported that incisor crowding and anterior maxillary irregularity had an impact on smiling, laughing and showing teeth without embarrassment.

Dental problems are widely recognized as affecting how patients feel about their teeth and smile. A study by van Palenstein Helderman and Mkasabuni (1993) examined the effect of dental fluorosis in Tanzania. The authors found that children with severe fluorosis suffered from feelings of worry which hindered their ability to smile and 91% of those children with severe fluorosis reported that they were prevented from smiling freely. However, a qualitative study by Marshman *et al.* (2009) which explored the everyday effects of developmental enamel defects in 21 adolescents found that the effects varied according to the “sense of self” rather than the extent of the enamel defects. Klages *et al.* (2004), in their study of young adults, also noted that the impact of malocclusion varied depending on the individual's own

self-awareness This was potentially the case in the current study too, where some participants were clearly more affected than others.

Interacting with people they know

In the current study, some participants stated that they had concerns about their dental appearance when interacting with people they already knew, although there was variation in the extent of this concern. A number of participants discussed being more worried with classmates than with friends or family, although some participants also worried what their friends would say.

Adolescents may worry about “being judged” and this is sometimes associated with the fear of becoming an outsider and induced feelings of sadness. It is important for young adolescents with malocclusions to feel socially comfortable without having to focus on their teeth (Taghavi Bayat *et al.*, 2013). Such negative biases of facial appearance can be observed as early as 10-11 years of age (O'Brien *et al.*, 2009; Seehra *et al.*, 2011b). Previous research has shown that individuals with normal incisor alignment were considered more desirable as friends, more attractive, intelligent, of higher social class and less aggressive in comparison with individuals with a malocclusion (Shaw *et al.*, 1980; Kerosuo *et al.*, 1995). Individuals with high levels of facial attractiveness have also been shown to receive a more favourable response from society compared with those with lower levels of facial attractiveness (Riggio and Woll, 1984; Cunningham, 1999). It is therefore not perhaps surprising that patients with malocclusions have concerns about interactions with others if such societal perceptions exist.

In the study mentioned earlier by Marshman *et al.* (2009), 21 participants (aged 10-15 years) were interviewed to explore the effect of development defects of enamel (DDE). The authors reported that the effects due to the DDE were worse in those people whose sense of self was dependent on their appearance and who “needed” perceived approval about their appearance from others. Some defined their social interactions as negative and despite having reasonable levels of self-esteem, reported that negative comments or questions from friends hurt them.

Meeting new people

In the current study, meeting new people did not represent a major concern for the majority of those interviewed as participants felt that new acquaintances would not comment on their teeth so did not feel too worried under these circumstances. However, one participant felt uncomfortable when meeting new people and was hopeful that orthodontic treatment would help them feel more confident in such situations.

The face, teeth and smile are often considered as being important in the development of first impressions when meeting new people and this first impression appears to be important for further communication (Josefsson *et al.*, 2010).

The face is considered an important communication tool, often portraying an individual's emotions and level of self-image. Modern society is controlled by the need to adhere to ideals and perceived dentofacial aesthetics can influence opinions formed of an individual by others (Shaw, 1981; Seehra *et al.*, 2011b). Moreover, the importance of having a good dentofacial appearance is also considered important when making friends (Linn, 1966; Cunningham, 1999). Making friends during adolescence is an essential part of their relationships. However, it is a dynamic process and is related to other factors, such as changes in the structure of the adolescent's networks, as well as to physical aspects (Ko and Buskens, 2011).

In the study by Marshman *et al.* (2009), described in the previous sections, participants discussed being asked questions about their teeth when meeting people for the first time and being asked whether the appearance of their teeth was due to poor oral hygiene and neglecting brushing them. Such questions affected their inter-personal interactions and they often sought treatment during the transition from primary to secondary school to avoid such questions.

Effects on school activities and out of school activities

There did not appear to be major effects on school activities and participants said they felt relatively comfortable in a school situation. Interestingly though, the majority of participants said that they felt more confident and less self-conscious when taking part in out of school activities than they did at school. This may be a reflection of the

high prevalence of teasing which takes place in the school environment. Research has focused on the teeth as a source of teasing among school children and this will be discussed in a later section (Shaw *et al.*, 1980a; Seehra *et al.*, 2011a; 2011b).

Some studies have investigated the effect of teeth and malocclusion on academic performance and suggested that children with better dental aesthetics had better interpersonal relationships and subsequently had higher levels of academic performance (Shaw *et al.*, 1980b). However, no studies were found regarding the effects of malocclusion on actual school activities to allow comparison with the current findings.

Theme 2: Feelings regarding facial images

Photographs

In this study, the majority of participants were self-conscious about their teeth when having photographs taken and this was clearly associated with negative feelings. Different terms were used by participants to express these feelings, especially if they were specifically asked to smile in photographs, and terms included: self-conscious, annoying and uncomfortable.

The perception that others see them differently due to the appearance of their teeth has also been highlighted in previous research. Shaw (1981) altered dental appearance on a standardized photograph of a young person smiling and showed the images to other young people. The authors found that the appearance of the teeth influenced social judgments made by their peers; however, dental appearance did not affect judgments made by teachers.

In a similar study by Taghavi Bayat *et al.* (2013), the authors reported that many participants expressed concern and avoided situations where they thought that their malocclusion might cause a problem, for example; the annual photo sessions for the school yearbook. The participants reported concerns that they would risk being made fun of or rejected by their peers.

Therefore, it is perhaps not surprising that the adolescents in this study felt uncomfortable in situations where photographs may be taken and they were likely to have experienced negative comments made under these circumstances.

Videos

The majority of participants did not worry about seeing themselves in videos, however one participant described how she felt “bad” seeing herself and her teeth in videos. In the Taghavi Bayat *et al.* (2013) study, participants were concerned about their teeth and malocclusion when they were video recorded and this was perceived as being “repeatedly reminded” of their malocclusion. Dissatisfaction with their teeth was often in their mind and this may become a key issue for adolescents.

Social media (Facebook and Instagram)

Several participants described feeling upset if someone posted a photograph of them on social media and their teeth were visible. A range of responses were described, including asking their friends or others to delete the image and feeling sad or “not too happy” if images were not deleted. Participants also discussed fears about being judged based on photographs which others could see readily through social media sites.

Similar findings were noted by Patel *et al.* (2016), who reported that many participants in their study felt “unhappy” and “upset” with their family or friends if they posted images on Facebook in which their teeth were visible.

The majority of participants discussed feeling self-conscious when having photographs taken but these feelings and responses appeared even “stronger” if the images were posted on social media. This was often associated with a need to protect their self-image in front of others, and participants often said that they would ask their friends to delete the photograph if they felt it might cause a problem for them. There is no doubt that we live in a society where social media plays an increasingly prominent role and it is therefore important that parents and clinicians are aware of these concerns. It is therefore important that clinicians are able to educate patients and parents about the negative feelings associated with social media and give advice on managing such situations.

Recently a new type of bullying called “cyber bullying” has developed, which involves bullying by sending text messages or e-mails through electronic devices

such as mobile phones and the Internet, and this is commonly seen among adolescents (Smith *et al.*, 2008). This is a real problem within this age group especially with the increasing use of electronic devices and the free communication through multimedia applications (Smith *et al.*, 2008; Seehra *et al.*, 2011b). This was not discussed in the current study but is something which parents and clinicians should be aware of and be able to offer advice on.

Facial appearance and mirrors

A number of participants discussed being aware that they were “different” in comparison with other people and that looking in mirrors highlighted that or made them feel insecure. A number of other qualitative studies have reported similar findings. Taghavi Bayat *et al.* (2013) discussed how negative thoughts or worries would emerge when participants looked at themselves in mirrors, especially during tooth brushing.

In the Marshman *et al.* (2009) study examining the effects of developmental defects of enamel (DDE), one participant reported that she started to think about her teeth when she moved to secondary school and looked in mirrors and thought she was different to her peers. Another participant mentioned that she did not want to look at herself in the mirror because she thought she looked “horrible”. Ryan *et al.* (2012) undertook a qualitative study of adult patients with dentofacial deformity and reported psychosocial impacts related to the social environment, such as feeling of hopelessness when looking in the mirror. To avoid such feelings, some patients reported avoiding looking in mirrors to reduce the levels of distress felt.

Theme 3: Teasing

Types

The majority of participants in this study reported being teased at some stage because of their teeth. Facial features and weight were found to be the most common causes of teasing in a previous study (Rieves and Cash, 1996) and teasing or bullying of young people due to the appearance of their teeth has now been reported in the literature in a number of different societies and cultures (Shaw *et al.*, 1982; Helm *et al.*, 1985; Shaw *et al.*, 1985; Seehra *et al.*, 2011, 2013; Al-Bitar *et al.*, 2013).

Both teasing and bullying are considered as aggressive behaviours (Olweus, 1994). Teasing is often considered as a milder form of aggressive behaviour with no significant harm intended to the recipient; however this did not appear to be the case in this study as there were some patients who were clearly affected by it and were annoyed or upset because of the teasing. Equally, there were others who accepted teasing as part of growing-up and were not distressed by it.

There are an increasing number of studies which have shown that malocclusion may be associated with teasing or bullying. Unaesthetic occlusal traits may induce unfavorable social responses among adolescents, such as nicknames and teasing resulting in potential disruption to normal psychological development (Johal *et al.*, 2007). These occlusal traits include spacing between the teeth, crowding, an increased overjet and deep overbite (Shaw *et al.*, 1980b; Seehra *et al.*, 2011b). Additional dental features found to be associated with bullying included dentoalveolar trauma and cleft lip/palate. Interestingly, one study undertaken a number of years ago suggested that severe facial disfigurement tended to evoke feelings of sympathy whereas milder disfigurements were more likely to result in teasing (Macgregor, 1970).

Different forms of teasing have been reported in the literature and name-calling is the most common type. In the present study, most of the respondents reported being teased verbally and talked about being called names, such as “buck teeth” and “horse teeth”. This was also found in a study by Kim *et al.* (2004) who reported that the most common types of bullying among middle school students were exclusion of other children (23%), followed by verbal comments (22%) and then physical abuse (16%).

In the current study, the reaction to teasing depended on the individual participants and some demonstrated more effective coping skills in these situations than others. Participants described different coping strategies such as ignoring the comments, trying to hide their teeth, trying to explain the problem, treating it as a joke and seeking family support. Others were clearly upset by the teasing they had experienced and would potentially benefit from support in these situations. This is an area where orthodontists could potentially provide advice and support.

Perpetrators: family, school, others

The majority of those participants who reported being teased, discussed this happening at school by classmates, although a small number reported teasing by relatives (for example, an uncle and a brother). Teasing was always by people they already knew. Importantly, not all participants reported being teased because of their teeth and this might be because their dental problem was mild or not visible. These findings were similar to other studies which reported that deviations in dental appearance are a target for teasing among schoolchildren. Other studies have found that the greater the deviation in the dental appearance, the greater the implication to the child. Studies reported that comments about teeth also appeared to be more hurtful than those about other features (Macgregor, 1970; Shaw *et al.*, 1980b; Seehra *et al.*, 2011a; Al-Bitar *et al.*, 2013).

The majority of participants discussed being teased when they were younger, however, some participants noted more teasing in secondary school. These findings are also consistent with other studies, which suggest that the incidence of teasing reduces with increasing age. With increasing age, children develop psychologically and physiologically and tend to become less vulnerable and less tolerant of aggressive behaviour (Olweus, 1994; Nansel *et al.*, 2001). In the UK, Boulton and Underwood (1992) found that 26% of 8 to 9 year-olds were bullied “sometimes or more often”, whilst this applied to only 15% of older children (11 to 12 year-old). In the USA, Nansel *et al.* (2001) conducted a study to assess bullying among adolescents in a cohort of 15,686 students from grades 6 to 10 who completed the World Health Organization’s-Health Behaviour Survey for School-aged children. They found that bullying was higher among students in grades 6 to 8 (11-13 years old) than among students in grades 9 and 10 (14-15 years old).

In the current study, a number of participants mentioned that they thought teasing was related to gender and they discussed that boys were more likely to be perpetrators of teasing than girls and they felt that this might be related to the more aggressive nature of boys. This finding concurs with several previous studies that revealed that both boys and girls may be exposed to teasing but boys were thought to be targets for teasing more frequently (Nansel *et al.*, 2001; Kim *et al.*, 2004; Seehra *et al.*, 2011b). Both males and females can be exposed to direct and indirect forms of bullying. However, males are more likely to face direct forms of aggression such as physical attacks and females appear to be exposed to more indirect types

such as spreading rumours, gossiping and isolation (Boulton and Underwood, 1992; Olweus, 1994).

Familial teasing was mentioned by some participants in the current study. It may be more painful to be teased by family members as home should be the place where children feel safe. Research has reported that familial teasing, especially from a father or older brother, was associated with negative outcomes in children (Keery *et al.*, 2005). Girls who reported appearance-related teasing by family members had lower self-esteem, a higher level of body dissatisfaction, negative social comparisons and depression than those who did not experience teasing (Keery *et al.*, 2005; Neumark-Sztainer *et al.*, 2010). However, other respondents in the current study reported that they had support from their family when they were exposed to teasing and this increased their confidence and ability to face such a problem.

Media influence

The effect of the media in relation to teasing was discussed by a small number of the participants. This may be because people consciously, or sub-consciously, compare their teeth with the ideals set by the media. However, this was also discussed in relation to watching a TV programme with a person who had the same dental problem as the interviewee and it made them concerned about their own problem.

There is little doubt that the media has an influence on adolescents (Thompson and Heinberg, 1999). Perceived media pressure in relation to teasing may have both negative and positive elements. It has been suggested that different sources of media, such as TV, newspapers and magazines have a strong impact on the way people think through daily focusing on specific facial features (Cellerino, 2003; Samsonyanova and Broukal, 2014). In the current study, one participant said that she watched a TV series where a girl had similar teeth and her inability to have orthodontic treatment, made the TV character feel sad and she tried to commit suicide. Such TV shows might make the audience more self-conscious about their concerns and therefore potentially affect psycho-social development. The media also routinely shows famous people with “perfect” teeth and this promotes the idea that people should have the same dental appearance.

In contrast, media coverage about teasing can highlight different anti-bullying policies and educate people about how to face this endemic problem. Media coverage, including national campaigns and social networking sites within the United Kingdom, have focused on the issue of bullying and brought it into the public domain. The impact of this is further highlighted by the finding that between 1997 and 1998, 17% of all calls received by Child Line were related to bullying (ChildLine annual review, 1997, 1998).

The findings of the current study suggest that teasing due to malocclusion may lead to adolescents being self-conscious, anxious and feeling insecure. It is important to highlight the issue of teasing in adolescents with malocclusion due to the potential psycho-social effects which may occur. Research has shown that there are short and long-term impacts due to teasing and persistent bullying can result in both physiological and psychological effects (Seehra *et al.*, 2011a). Schwartz *et al.* (1993) reported that those who are bullied or teased may develop depressive tendencies that can persist into adulthood, even after the teasing stops. Similarly, Olweus (1994) found that seriously bullied children suffered persistently low self-esteem and depression as young adults. In particular, bullied girls appeared more likely to develop mental health problems than boys and this might be related to the increased frequency of indirect bullying in girls (Rigby, 1999).

Despite the differences between studies in reporting the causes and effects of teasing, in orthodontics almost all studies have found a relationship between certain occlusal features and teasing. Therefore, dentists and orthodontists have a responsibility to identify children who may be being subjected to persistent teasing because of their dental problems and to offer them support or early orthodontic treatment if that might help. However, for more serious situations, or if early treatment is not possible, the situation may be better handled by suitably trained professionals or by seeking advice from anti bullying organisations. Information should be easily available in schools and dental clinics/departments through posters and leaflets to educate people.

4.5 Conclusions

The following conclusion may be drawn from this study:

- There was marked individual variation regarding the issues which were discussed, however, three main themes were identified relating to the social impacts of malocclusion: interpersonal relations, feelings regarding facial images and teasing.
- One issue of concern for the adolescents interviewed was that they were repeatedly reminded of their malocclusion. This seemed to be reinforced through the use of social media and people making comments or teasing them; this was further reinforced through the media.
- This study also highlighted the importance of addressing the problem of teasing and bullying among adolescents. The present findings add to our understanding of the emotional distress adolescents with malocclusion may be experiencing. It also underlines the importance of clinicians being familiar with the issues that may affect patients and being able to identify which patients may need additional support and where this support is available.

4.5.1 Clinical implications

The findings of this study reinforced the importance of considering how malocclusion might affect social aspects of life in adolescent orthodontic patients. It must be borne in mind that the study involved a relatively small number of respondents and a limited number of patients with each type of incisor relationship, however, the study provides an insight into the social impacts of malocclusion.

It is important to consider that the severity and need for orthodontic treatment within the UK is judged based on occlusal and aesthetic impairment (the IOTN system). The present study supports the importance of incorporating psychosocial factors into current and future indices.

The effect of malocclusion on OHRQoL should also be considered and an increasing number of studies have reported a relationship between malocclusion

and negative impacts on an individual's OHRQoL. This study has shown that malocclusion has a significant impact on the emotional and social domains, including impacts on interpersonal relationships, concerns regarding having photographs taken and concerns regarding teasing about dentofacial appearance. This provides further support for the suggestion that the presence of a malocclusion has significant psycho-social effects. Clinicians should be aware that their patients may feel self-conscious and should be sensitive when asking questions and discussing treatment with them.

It is perhaps not surprising that teasing and bullying affect an individual both emotionally and socially and comments regarding dental appearance have been reported to be more hurtful and upsetting in comparison with teasing about other physical features (Shaw *et al.*, 1980; O'Brien *et al.*, 2001; O'Brien *et al.*, 2006). Therefore, patients who are teased or bullied due to the presence of a malocclusion may well experience negative impacts on their oral-health-related quality of life (OHRQoL) (Seehra *et al.*, 2013). Early interceptive orthodontic treatment may help some patients (Seehra, *et al.*, 2011) and this should be considered where possible. If this is not feasible, then patients and their parents should be advised about the different support organisations in the UK (for example www.bullying.co.uk) and this information should be readily available in waiting rooms.

Overall summary of the thesis

The qualitative chapter in this thesis showed that there are social impacts as a result of having a malocclusion, although there was marked individual variation. However, the effects of orthodontic treatment remain less clear-cut. The results of the systematic review were unable to support or refute quality of life and/or psychosocial changes as a result of treatment. Additionally, the longitudinal clinical study did not find any evidence of significant social benefits associated with functional appliance treatment based on the questionnaires selected.

However, the systematic review highlighted aspects, which may allow future research to control for some of these limitations. The longitudinal clinical study (Chapter III) followed some of these suggestions and included sample size calculations based on the psycho-social outcomes but was not able to include robust condition-specific questionnaires as none were available at that time point. However, the recent publication of a QoL questionnaire for orthodontic patients (Benson *et al.*, 2016; Patel *et al.*, 2016) means that condition specific measures are now available and future research should focus on developing a small number of high quality questionnaire to be used in this field of research.

The conflicting results of the studies in this Ph. D highlighted the complexity of studying social impacts of malocclusion and orthodontic treatment. The evaluation of social and cultural effects, however, requires the use of heterogeneous samples with adequate variations in factors, such as: ethnicity, cultural, education and socio-economic status. Such evaluation is difficult in clinical studies in orthodontics, because children are belongs to the same standards. Therefore, future studies should incorporate different social factors into a large study.

General discussion and considerations for future research

- One of the key strengths of randomised controlled trials (RCTs) in medical research comes from its potential to reduce bias through aspects such as blinding. Many researchers have called for more randomised controlled trials (RCTs) in orthodontics. However, ethical issues frequently preclude RCTs and there are issues relating to the difficulties of blinding clinicians and patients in many clinical studies. High quality prospective observational cohort studies with longitudinal follow-up are a useful alternative to RCTs and the use of such studies should be encouraged in orthodontics. As highlighted in Chapter II, the importance of then basing sample size calculations on the psychosocial measure(s) reduces the risk of underpowered studies and multi-centred studies should also be considered to ensure that larger sample sizes can be achieved.
- Research involving observation of cohorts of orthodontic patients allows relationships between an independent and dependent variables to be studied in detail and, in future studies, it would be beneficial to further investigate the effects of maturation, the patient's age, type and severity of malocclusion, their personality characteristics, perception of his/her malocclusion, and the impact of family and significant others. Additionally, questionnaires should be distributed at standardised time point. This will require larger numbers of patients as more variables are included and,, as mentioned in the previous bullet, multi centre studies may assist with this.
- Further development of questionnaires which can be used in research into malocclusion and orthodontic treatment is important. These measures should be psychometrically robust and internationally accepted and should also be relatively short to prevent participant fatigue. By agreeing on the use of a small number of condition-specific questionnaires in this field of research, it should be feasible to undertake meta-analyses in the future.

Although quantitative research has many advantages, the context of the research is not always easy to consider and subjective issues are difficult to quantify; his is where qualitative studies become particularly important.

Qualitative research is relatively new in orthodontics but is becoming increasingly popular. One area of research which may prove useful would be to undertake longitudinal qualitative studies to explore and understand the social impacts of malocclusion and orthodontic treatment in greater detail. Mixed methods research, including both quantitative and qualitative methods, has the very real benefit of being able to balance the limitations of one methodology with the strengths of another.

- Currently the severity and need of orthodontic treatment within the UK is judged on occlusal and aesthetic impairment without consideration of psychosocial factors. It is recommended that the latter should be incorporated into current and future indices to allow these psycho-social effects to be considered. This should be a priority for research in orthodontics.

Appendices

Appendix 1: Search strategy for systematic review investigating the psycho-social impacts of orthodontics treatment in adolescent patients

Medline via Ovid

1. exp Orthodontics/
2. Orthodonti*.mp.
3. ((appliance* or device* or brace*) adj5 (fix* or remov* or function* or orthop?edic*)).mp.
4. (Dental* adj3 (appearance* or aesthetic* or esthetic* or treatment*)).mp.
5. 1 or 2 or 3 or 4
6. exp Psychology/
7. Psycholog*.mp.
8. (Psychosocial* or psycho-social*).mp.
9. exp Self-concept/
10. Self-concept*.mp.
11. Self-esteem*.mp
12. Self assessment*.mp.
13. Self evaluat*.mp.
14. Social impact*.mp.
15. Social influenc*.mp.
16. exp Perception/
17. Perception*.mp.
18. Social disabilit*.mp.
19. Social anxiet*.mp.
20. Social adjust*.mp.
21. Social activit*.mp.
22. exp Social Behavior/
23. Social behavio?r*.mp.
24. Social isolation*.mp.
25. Social interact*.mp.
26. Social adapt*.mp.
27. Social chang*.mp
28. exp "Quality of Life"/
29. (Quality of life* or qol) .mp.
30. exp Interpersonal Relations/
31. Interpersonal relation*.mp.
32. Interpersonal interact*.mp
33. Interpersonal communicat*. mp
34. Peer relation*.mp
35. Peer interact*.mp.
36. Friendship*.mp
37. Human relation*
38. exp Patient Satisfaction/
39. Patient satisfaction*.mp.
40. (Patient based outcome* or patient centred outcome* or patient centered outcome*).mp.
41. exp Phobic Disorders/
42. Phobic disorder*.mp.
43. Body image*.mp.
44. Stress*.mp.
45. exp Depression/
46. Depression*.mp.

47. exp Bullying/
48. Bully*.mp.
49. Teasing*.mp
50. exp Emotions/
51. Emotion*.mp.
52. exp Compulsive Behavior/
53. Compulsive behavio?r*.mp.
54. Obsessive behavio?r*.mp.
55. exp Mental Health/
56. Mental health.mp.
57. exp Personality/
58. Personalit*.mp.
59. Well being* or wellbeing*.mp.
60. or/6-59
61. 5 and 60
62. limit 61 to yr="1980 -Current"
63. limit 62 to ("child (6 to 12 years)" or "adolescent (13 to 18 years)")
64. randomized controlled trial.pt.
65. controlled clinical trial.pt.
66. randomized.ab.
67. placebo.ab.
68. drug therapy.fs.
69. randomly.ab.
70. trial.ab.
71. groups.ab.
72. or/64-71
73. exp animals/ not humans.sh.
74. 72 not 73
75. 63 and 74
76. Epidemiologic studies/
77. Exp case control studies/
78. Exp cohort studies/
79. Case control.tw.
80. (cohort adj (study or studies)).tw.
81. Cohort analy\$.tw.
82. (Follow up adj (study or studies)).tw.
83. (observational adj (study or studies)).tw.
84. Longitudinal.tw.
85. Retrospective.tw.
86. Cross sectional.tw.
87. Cross-sectional studies/
88. Or/76-87
89. 63 and 88
90. 75 or 89

PsyclINFO

1. exp Dental Treatment/
2. Dental treatment*.mp
3. Orthodonti*.mp.
4. ((appliance* or device* or brace*) adj5 (fix* or remov* or function* or orthop?edic*))
5. (dental* adj3 (appearance* or aesthetic* or esthetic*)).mp.
6. 1 or 2 or 3 or 4 or 5
7. exp Psychology/
8. Psycholog*.mp.
9. (psychosocial* or psycho-social*).mp.
10. exp Self-concept/
11. Self-concept*.mp.

12. Self-esteem*.mp.
13. exp Self Evaluation/
14. (self evaluat* or self assessment*).mp.
15. exp Social Influences/
16. (social influenc* or social impact*).mp.
17. exp Perception/
18. perception*.mp
19. Social disabilit*.mp
20. exp Social Anxiety/
21. Social anxiet*.mp.
22. exp Social Adjustment/
23. Social adjust*.mp.
24. (Social interact* or social activit*).mp.
25. exp Social Behavior/
26. (social behavio?r*).mp.
27. Social isolation*.mp.
28. Social adapt*.mp
29. Social chang*
30. exp "Quality of Life"/
31. Quality of life* or qol.mp.
32. exp Interpersonal Relationships/
33. (interpersonal relation* or interpersonal interact* or interpersonal communicat*).mp.
34. exp Peer Relations/
35. (Peer relation* or friendship* or peer interact* or human relation*).mp.
36. Patient satisfaction*.mp.
37. (Patient based outcome* or patient centred outcome* or patient centered outcome*).mp.
38. Phobic Disorder*.mp.
39. exp Body Image/
40. Body Image*.mp.
41. exp Stress/
42. Stress*.mp.
43. Depression*.mp.
44. exp Bullying/
45. Bully*.mp.
46. Teasing*.mp.
47. exp Emotions/
48. Emotion*.mp.
49. Compulsive behavio?r*.mp.
50. Obsessive behavio?r*.mp.
51. exp Mental Health/
52. Mental Health.mp.
53. exp Personality/
54. Personalit*.mp.
55. (Well being* or wellbeing*).mp
56. Or/7-55
57. 6 and 56
58. limit 57 to yr="1980 -Current"
59. limit 58 to (180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>)
60. control:.tw.
61. random:.tw.
62. exp treatment/
63. or/60-62
64. 59 and 63
65. (case control study or case report or case reports or case study or case control studies or clinical study or cohort analysis or cohort studies or correlational study or cross sectional studies or cross sectional study or epidemiologic studies or family study or follow up or followup studies or

follow up studies or hospital based case control study or longitudinal studies or longitudinal study or observational study or population based case control study or prospective studies or prospective study or retrospective studies or retrospective study).sh

66. (((case or crosssectional or cross sectional or epidemiologic\$ or observational) adj (study or studies)) or (case adj (control\$ or report\$)) or cohort\$1 or cross sectional or followup\$ or follow up\$ or followed or longitudinal\$ or prospective\$ or retrospective\$).tw.

67. case reports.pt.

68. Or/65-67

69. 59 and 68

70. 64 or 69

Web of Science

1. TS=(orthodonti*)
2. TS=Dental treatment*
3. TS=(fixed appliance* or fixed brace* or fixed device*)
4. TS=(removable appliance* or removable device* or removable brace*)
5. TS=(functional appliance* or functional device* or functional brace*)
6. TS=(orthop*edic appliance* or orthop*edic device* or orthop*edic brace*)
7. TS=(Dental appearance* or dental aesthetic* or dental esthetic*)
8. #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
9. TS=psycholog*
10. TS=psychosocial*
11. TS=(self-concept* or self-esteem*)
12. TS=(self assessment* or self evaluat*)
13. TS=social impact*
14. TS=Perception*
15. TS=social disabilit*
16. TS=social anxiet*
17. TS=(social interact* or social Adjust*)
18. TS=social activit*
19. TS=social behavio*r*
20. TS=Social Isolation*
21. TS=Social influenc*
22. TS=(Social adapt* or social chang*)
23. TS=(Quality of Life OR qol)
24. TS=(Interpersonal Relation* or Interpersonal interact* or interpersonal communicat* or human relation*)
25. TS=(peer relation* or peer interact* or friendship*)
26. TS=Patient Satisfaction*
27. TS=patient based outcome*
28. TS=(patient centred outcome* or patient centered outcome*)
29. TS=(Phobic Disorder* or body image*)
30. TS=(emotion* or stress* or depression*)
31. TS=(bully* or teasing*)
32. TS=(compulsive behavio*r* or obsessive behavio*r*)
33. TS=(mental health or personalit* or well-being* or wellbeing*)
34. #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9
35. TS=(adolescent* or young adult* or child* or teenager*)
36. TS=(clinical trial* OR research design OR comparative stud* OR evaluation stud* OR controlled trial* OR follow-up stud* OR prospective stud* OR random* OR placebo* OR (single blind*) OR (double blind*))
37. #36 AND #35 AND #34 AND #8
38. TS=(case* control* stud* OR case* comparison* OR case report* or control

group* or crosssectional stud* or cross sectional stud* or clinical stud* or cohort stud* or cohort analys* or epidemiologic* stud* or observational stud* or longitudinal stud* or prospective stud* or retrospective stud* OR followup stud* or follow up stud* or Clinical Case Stud* or empirical stud*)

39. 38 and 35 and 34 and 8

40. 37 or 39

Embase

1. exp orthodontics/
2. orthodonti*.mp.
3. Dental treatment*.mp.
4. ((appliance* or device* or brace*) adj5 (fix* or remov* or function* or orthopaedic*)).mp.
5. (dental* adj3 (appearance* or aesthetic* or esthetic*)).mp.
6. 1 or 2 or 3 or 4 or 5
7. exp psychology/
8. psycholog*.mp.
9. (psychosocial* or psycho-social*).mp.
10. exp self-concept/
11. self-concept*.mp.
12. self-esteem*
13. exp self evaluation/
14. self evaluat*.mp.
15. self assessment*.mp.
16. (social influenc* or social impact*).mp.
17. exp perception/
18. perception*.mp.
19. social disabilit*.mp.
20. social anxiet*.mp.
21. (social adapt* or social chang*).mp.
22. social adjust*.mp.
23. social interact*.mp.
24. exp social behavior/
25. (social behavior?r*).mp.
26. exp social isolation/
27. social isolation*.mp.
28. exp "quality of life"/
29. quality of life* or qol .mp.
30. exp human relation/
31. human relation*.mp.
32. (interpersonal adj2 (relation* or communicat* or interact*)).mp.
33. (peer interact* or peer relation* or friendship*).mp.
34. exp patient satisfaction/
35. patient satisfaction*.mp.
36. (patient based outcome* or patient centred outcome* or patient centered outcome*).mp.
37. Phobic Disorder*.mp.
38. body Image*.mp.
39. stress*.mp.
40. depression*.mp.
41. bully*.mp.
42. teasing*.mp.
43. exp emotion/
44. emotion*.mp.
45. compulsive behavior?r*.mp.
46. obsessive behavior?r*.mp.

47. exp mental health/
48. mental health*.mp.
49. exp personality/
50. personalit*.mp.
51. exp wellbeing/
52. wellbeing* or well being*.mp.
53. or/7-52
54. 6 and 53
55. limit 54 to yr="1980 -Current"
56. limit 557 to (school child <7 to 12 years> or adolescent <13 to 17 years>)
57. Clinical trial/
58. Randomized controlled trial/
59. Randomization/
60. Single blind procedure/
61. Double blind procedure/
62. Crossover procedure/
63. Placebo/
64. Randomi?ed controlled trial\$.tw.
65. Rct.tw.
66. Random allocation.tw.
67. Randomly allocated.tw.
68. Allocated randomly.tw.
69. (allocated adj2 random).tw.
70. Single blind\$.tw.
71. Double blind\$.tw.
72. ((treble or triple) adj blind\$.tw
73. Placebo\$.tw.
74. Prospective study/
75. Or/57-74
76. Case study/
77. Case report.tw.
78. Abstract report/ or letter/
79. Or/76-78
80. 75 not 79
81. 56 and 80
82. Clinical study/
83. Case control study
84. Family study/
85. Longitudinal study/
86. Retrospective study/
87. Prospective study/
88. Randomized controlled trials/
89. 87 not 88
90. Cohort analysis/
91. (Cohort adj (study or studies)).mp.
92. (Case control adj (study or studies)).tw.
93. (follow up adj (study or studies)).tw.
94. (observational adj (study or studies)).tw
95. (epidemiologic\$ adj (study or studies)).tw.
96. (cross sectional adj (study or studies)).tw.
97. Or/82-86,89-96
98. 56 and 97
99. 81 or 98

1. MeSH descriptor: (Orthodontics)
2. Orthodonti
3. Dental treatment*
4. (appliance or device or brace) adj5 (fix or remov or function or orthopaedic)
5. dental adj3 (appearance* or aesthetic* or esthetic*)
6. {OR #1-#5}
7. MeSH descriptor: (Psychology)
8. Psychology
9. psychosocial or psycho-social
10. MeSH descriptor: (Self-concept)
11. self-concept
12. self-esteem
13. self evaluation
14. MeSH descriptor:(self assessment)
15. self assessment
16. MeSH descriptor:(social change)
17. social change
18. social impact
19. social influence
20. MeSH descriptor:(perception)
21. Perception
22. social disability
23. social anxiety
24. social adaptation
25. MeSH descriptor: (social adjustment)
26. social adjustment
27. MeSH descriptor: social behavior
28. Social behavior
29. MeSH descriptor: (social isolation)
30. Social isolation
31. MeSH descriptor: (quality of life)
32. Quality of life
33. Qol
34. MeSH descriptor: (Interpersonal Relations)
35. Interpersonal relation
36. social interaction or interpersonal interaction or interpersonal communication or human relation
37. Peer interaction
38. Peer relation
39. Friendship
40. MeSH descriptor: (patient satisfaction)
41. Patient satisfaction
42. Patient based outcome or patient centred outcome
43. MeSH descriptor: (phobic disorders)
44. Phobic disorder
45. Body image
46. Stress
47. MeSH descriptor: (depression)
48. Depression
49. MeSH descriptor: (Bullying)
50. Bully
51. Teasing
52. MeSH descriptor: (emotions)
53. Emotion
54. MeSH descriptor: (compulsive behavior)

55. compulsive behavior
56. MeSH descriptor: (obsessive behavior)
57. Obsessive behavior
58. MeSH descriptor: (mental health)
59. Mental health
60. MeSH descriptor:(personality)
61. Personality
62. Well being or wellbeing
63. {OR #7-#62}
64. #6 and #63
65. adolescent or young adult or child or teenager
66. #64 and #65
67. #66 from 1980 to 2013
68. #67 in Trials

LILACS

Orthodontics or dental treatment or removable appliance or removable device or removable brace or fixed appliance or fixed device or fixed brace or functional appliance or functional device or functional brace or orthopedic appliance or orthopedic device or orthopedic brace or appearance or aesthetic (Subject descriptor) and psychology or psychosocial or self-concept or self-esteem or self evaluation or self assessment or social influence or social impact or perception or social disability or social anxiety or social activity or social adaptation or social adjustment or social interaction or social behavior or social isolation or social change or quality of life or human relation or interpersonal relation or interpersonal communication or interpersonal interaction or peer interaction or peer relation or friendship or patient satisfaction Or patient based outcome or patient centred outcome or patient centered outcome or Phobic Disorder Or body image or stress or depression or bully or emotion or compulsive behavior or obsessive behavior or mental health or personality or wellbeing (Subject descriptor) and adolescent or young adult or child or teenager (Subject descriptor)

Orthodontic or dental treatment or removable appliance or removable device or removable brace or fixed appliance or fixed device or fixed brace or functional appliance or functional device or functional brace or orthopedic appliance or orthopedic device or orthopedic brace or orthopaedic appliance or orthopaedic device or orthopaedic brace or appearance or aesthetic and psychology or psychosocial or psycho-social or self-concept or self-esteem or self evaluation or self assessment or social influence or social impact or perception or social disability or social anxiety or social activity or social adaptation or social adjustment or social interaction or social behavior or social behaviour or social isolation or social change or quality of life or qol or human relation or interpersonal relation or interpersonal communication or interpersonal interaction or peer interaction or peer relation or friendship or patient satisfaction or patient based outcome or patient centred outcome or patient centered outcome or Phobic disorder Or body image or stress or depression or bully or emotion or compulsive behavior or compulsive behaviour or obsessive behavior or obsessive behaviour or mental health or personality or wellbeing or well being or well-being and adolescent or young adult or child or teenager

Appendix 2: The data extraction sheet for the systematic review investigating QoL and psycho-social impacts of orthodontic treatment in adolescent patients

Data Extraction Sheet Full –text article				
Psycho-social impacts of Orthodontic treatment in adolescents				
<div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div>				
<div style="border: 1px solid black; min-height: 100px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div>				
<div style="border: 1px solid black; min-height: 100px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; min-height: 60px; margin-bottom: 5px;"></div>				
<div style="display: flex; justify-content: space-around; margin-bottom: 10px;"> STUDY INCLUDED STUDY EXCLUDED </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>				

Study Eligibility				
	Factors	Assessment		
Type of study	Randomized Clinical Trial	Yes	No	Unclear
	Observational study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants	Were participants diagnosed as having a malocclusion?	Yes	No	Unclear
	Does the study include male and/or female adolescents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Were participants of the specified age?	Yes	No	Unclear
Type of Intervention	Have the patients undergone orthodontic treatment with:	Yes	No	Unclear
	1. Removable appliances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	2. Fixed appliances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3. Functional appliances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	4. Headgear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5. Any combination of these reported in the literature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Outcomes	Did the study report the specified outcomes?	Yes	No	Unclear
Final Decision	No to any of the above rejects study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	INCLUDE <input type="checkbox"/> EXCLUDE <input type="checkbox"/>			

Reasons for rejection (please specify according to protocol)	
Methods	
Participants	
Intervention	
Outcomes	
Others	

Do not proceed if the study is excluded from the review

Characteristics of included studies

Study Characteristics				
Primary study aims				
Secondary study aims				
Study design		Yes	No	Unclear
	Randomized Clinical Trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Observational study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-Case series	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-Cohort study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-Case control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-Other (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Retrospective	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Prospective	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Longitudinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Cross sectional	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inclusion/ exclusion criteria specified		Yes	No	Not specified
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethical approval obtained for study		Yes	No	Not specified
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Funding		Yes	No	Not specified
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		If yes, where from?		
Sample size calculation		Yes	No	Not specified
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study setting		Hospital	Practice	Not-specified
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Country				
Duration of participation /follow-up (from recruitment to last follow-up)				
Notes:				

Demographic Data

	Treatment group (Gp1)	Treatment group (Gp2)	Control group	Total
Number of participants				
Age	Range	Range	Range	Range
	Mean	Mean	Mean	Mean
	Median	Median	Median	Median
	SD	SD	SD	SD
Gender	Male	Male	Male	Male
	Female	Female	Female	Female
Ethnicity				
Notes				

	Treatment group (Gp1)	Treatment group (Gp2)	Control group
Types	Skeletal	Skeletal	
	Anterior-Posterior	Anterior-Posterior	Normal occlusion <input type="checkbox"/>
	Skeletal I <input type="checkbox"/>	Skeletal I <input type="checkbox"/>	Malocclusion <input type="checkbox"/>
	Skeletal II <input type="checkbox"/>	Skeletal II <input type="checkbox"/>	Delayed treatment <input type="checkbox"/>
	Skeletal III <input type="checkbox"/>	Skeletal III <input type="checkbox"/>	No treatment <input type="checkbox"/>
	Not specified <input type="checkbox"/>	Not specified <input type="checkbox"/>	
	Vertical	Vertical	If there is malocclusion, which type?
	High MMPA <input type="checkbox"/>	High MMPA <input type="checkbox"/>	Skeletal
	Low MMPA <input type="checkbox"/>	Low MMPA <input type="checkbox"/>	Anterior-Posterior
	Average MMPA <input type="checkbox"/>	Average MMPA <input type="checkbox"/>	Skeletal I <input type="checkbox"/>
	Not specified <input type="checkbox"/>	Not specified <input type="checkbox"/>	Skeletal II <input type="checkbox"/>
	Transverse	Transverse	Skeletal III <input type="checkbox"/>
	Symmetry <input type="checkbox"/>	Symmetry <input type="checkbox"/>	Not specified <input type="checkbox"/>
	Asymmetry <input type="checkbox"/>	Asymmetry <input type="checkbox"/>	Vertical
	Not specified <input type="checkbox"/>	Not specified <input type="checkbox"/>	High MMPA <input type="checkbox"/>
			Low MMPA <input type="checkbox"/>
			Average MMPA <input type="checkbox"/>
			Not specified <input type="checkbox"/>
	Incisor Classification	Incisor Classification	Transverse
	CI I <input type="checkbox"/>	CI I <input type="checkbox"/>	Symmetry <input type="checkbox"/>
	CI II div 1 <input type="checkbox"/>	CI II div 1 <input type="checkbox"/>	Asymmetry <input type="checkbox"/>
	CI II div 2 <input type="checkbox"/>	CI II div 2 <input type="checkbox"/>	Not specified <input type="checkbox"/>
	CI III <input type="checkbox"/>	CI III <input type="checkbox"/>	
Not specified <input type="checkbox"/>	Not specified <input type="checkbox"/>	Incisor Classification	
		CI I <input type="checkbox"/>	
		CI II div 1 <input type="checkbox"/>	
		CI II div 2 <input type="checkbox"/>	
		CI III <input type="checkbox"/>	
		Not specified <input type="checkbox"/>	
Number of drop-outs			
Reasons for drop-outs (Please say if not specified)			

Treatment Details						
Treatment performed	Removable appliances	<input type="checkbox"/>	Upper	<input type="checkbox"/>		
			Lower	<input type="checkbox"/>		
	Fixed appliances	<input type="checkbox"/>	Upper	<input type="checkbox"/>		
			Lower	<input type="checkbox"/>		
	Headgear	<input type="checkbox"/>	Conventional	<input type="checkbox"/>		
		Protraction Headgear (Facemask)	<input type="checkbox"/>			
Functional appliances	<input type="checkbox"/>	(Specify type of appliance)				
Duration of treatment	Mean					
	Median					
	SD					
	95% CI					
Duration of follow-up	Mean					
	Median					
	SD					
	95% CI					
Observational interval (Months/years)	T1	T2	T3	T4	T5	T6

Outcome Measures (Tick as appropriate)							
		T1		T2		T3	
		Patients	Control	Patients	Control	Patients	Control
Examinations	Clinical Examinations						
	Study models						
	Lateral cephalogram						
	TMJ examination						
Questionnaires	Psycho-social measures						
	Piers-Harris Self-concept Scale						
	Multidimensional Self-concept Scale						
	Tennessee Self-concept Scale						
	Coppens Self-Esteem Scale						
	Rosenberg Self-esteem Scale						
	Global Negative Self-Evaluation Scale						
	Harter's Self-Perception Profile for children						
	Harter's Self-Perception Profile for adolescents						
	Other (please specify)						
	ORHQR measures						
	Child Perception Questionnaire (CPQ 11-14)						
	The Oral Aesthetic Subjective Impact Scale (OASIS)						
	The Oral Health Impact Profile (OHIP-14)						
	The Oral Health Impact Profile (OHIP-20)						
	The Oral Health Impact Profile (OHIP-49)						
	Oral Health Quality of Life (OHQOL-UK)						
	Oral Impacts on Daily Performances (OIDP)						
	The Child Oral Health Quality of Life (COHQOL)						
	Other (please specify)						

Results						
Questionnaire 1						
Primary outcome The social, psychological and/or QoL effects as a result of orthodontic treatment.						
Total	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						
Subscales	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
P-values/ significance of the findings						
Secondary outcome Including any gender and/or ethnicity effects.						
	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						

Results						
Questionnaire 2						
Primary outcome The social, psychological and/or QoL effects as a result of orthodontic treatment.						
Total	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						
Subscales	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
P-values/ significance of the findings						
Secondary outcome Including any gender and/or ethnicity effects.						
	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						

Results						
Questionnaire 3						
Primary outcome The social, psychological and/or QoL effects as a result of orthodontic treatment.						
Total	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						
Subscales	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
P-values/ significance of the findings						
Secondary outcome Including any gender and/or ethnicity effects.						
	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						

Results						
Questionnaire 4						
Primary outcome The social, psychological and/or QoL effects as a result of orthodontic treatment.						
Total	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						
Subscales	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
P-values/ significance of the findings						
Secondary outcome Including any gender and/or ethnicity effects.						
	T1		T2		T3	
	Patients	Control	Patients	Control	Patients	Control
Mean						
Median						
Range						
SD						
95% CI						
Other						
P-values/ significance of the findings						

Outcomes	
ITT	Yes No
Statistically significant	
If outcomes was NOT statistically significant is it because due to	
Evidence of absence of treatment effect	
No evidence for absence of treatment effect	
Unclear	

Appendix 3: Cochrane RCTs Quality Assessment

Risk of bias				
Domain	Support for judgment	Review authors' judgement		
Selection bias.				
Random sequence generation.		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Allocation concealment		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Performance bias.				
Blinding of participants and personnel <i>Assessments should be made for each main outcome (or class of outcomes).</i>		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Detection bias.				
Blinding of outcome assessment <i>Assessments should be made for each main outcome (or class of outcomes).</i>		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Attrition bias.				
Incomplete outcome data <i>Assessments should be made for each main outcome (or class of outcomes).</i>		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Reporting bias.				
Selective reporting.		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
Other bias.				
Other sources of bias: <i>(e.g.: sample size calculation)</i>		Low risk <input type="checkbox"/>	High risk <input type="checkbox"/>	Unclear risk <input type="checkbox"/>
The overall risk of bias of the included study				
<div> <div>Low risk</div> <div>High risk</div> <div>Unclear risk</div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> </div>				

Appendix 4: The Modified version-Newcastle Ottawa Quality Assessment Scale (Observational study)

Selection		
1) Representativeness of the exposed/treatment cohort a) Truly representative of the average _____ (Describe) in the community ● b) Somewhat representative of the average _____ in the community ● c) Selected group of users e.g. volunteers d) No description of the derivation of the cohort	Low risk	High risk
2) Selection of the non-exposed/control cohort a) Drawn from the same community as the exposed cohort● b) Drawn from a different source c) No description of the derivation of the non-exposed cohort	Low risk	High risk
3) Ascertainment of exposure (orthodontic treatment) a) Secure record (e.g. dental records; confirmation from clinician) ● b) Clinical examination with/without reference to previous records c) Self report d) No description	Low risk	High risk
4) Demonstration that outcome of interest was present at start of study (is there data for at least 2 time points - one prior to any intervention and one after?) a) Yes ● b) No	Low risk	High risk
5) Was sample size calculation described? If no, is it adequately justified? a) Yes ● b) No	Low risk	High risk
Comparability		
1) Comparability of cohorts on the basis of the design or analysis a) Study controls for _____ age _____ ● b) Study controls for any additional factor _____ gender _____ ●	Low risk	High risk
Outcome		
1) Validity of the outcome measure a) Questionnaire, which has been validity and reliability tested/published ● b) Researcher developed questionnaire (the validity and reliability not tested/published) c) Unclear	Low risk	High risk
2) Assessment of outcome a) Independent completion of questionnaire (eg. in study setting, no input from researcher or family member) ● b) Completion of questionnaire without reporting of independent completion (e.g. could be completed at home; potential input from researcher or family member) c) No description	Low risk	High risk
3) Was follow-up long enough for outcomes to occur a) Yes (at least 6 months post/diagnosis) ● b) No c) No follow-up (only one time point/cross-sectional study)	Low risk	High risk
4) Adequacy of follow up of cohorts a) Complete follow up - all subjects accounted for ● b) Subjects lost to follow up unlikely to introduce bias - small number lost; < 20 % dropout rate, or adequate description provided of those lost ● c) > 20 % dropout rate d) No statement or no follow-up (only one time point/cross-sectional)	Low risk	High risk
Other bias		
Other sources of bias		
The overall risk of bias of the included study		
<div>Low risk</div> <div>High risk</div> <div> <input type="checkbox"/> <input type="checkbox"/> </div>		

Appendix 5: Ethical approval for the longitudinal clinical study (Chapter III)



NRES Committee London - Chelsea

HRA
Research Ethics Committee (REC) London Centre
Ground Floor
80 Skipton House
London Road
London, SE1 6LH

Telephone: 020 7972 2556

28 October 2013

Professor Susan Cunningham
Professor/Hon Consultant in Orthodontics
UCL, Department of Orthodontics
UCL Eastman Dental Institute
256 Grays Inn Road, London
WC1X 8LD

Dear Professor Cunningham

Study title: A prospective controlled questionnaire study to investigate the psychosocial effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents
REC reference: 13/LO/1256
IRAS project ID: 128743

Thank you for your letter of 08 October 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 01 November 2013. A list of the members who were present at the meeting is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mr Thomas McQuillan, nrescommittee.london-chelsea@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Investigator CV		07 June 2013
Other: CV: Professor Nigel Peter Hunt		03 July 2013
Other: CV: Dr Huda Abutayyem		07 June 2013
Other: Patient Information Leaflet	1	01 October 2013
Participant Consent Form: Control - Parent	2	08 October 2013
Participant Consent Form: Control - Patient	2	08 October 2013
Participant Consent Form: Functional Group - Parent	2	08 October 2013
Participant Consent Form: Functional Group - Patient	2	08 October 2013
Participant Information Sheet: Control - Parent	2	08 October 2013
Participant Information Sheet: Control - Patient	2	08 October 2013
Participant Information Sheet: Functional Group - Parent	2	08 October 2013
Participant Information Sheet: Functional Group - Patient	2	08 October 2013
Protocol	2	08 October 2013
Questionnaire: Record Booklet		08 October 2013
REC application	128743/4764 18/1/783	12 July 2013
Response to Request for Further Information		08 October 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/LO/1256

Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Dr Shelley Dolan


Chair

Email: nrescommittee.london-chelsea@nhs.net

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: Miss Tabitha Kavoi, Senior Portfolio Coordinator, Joint Research Office,
UCLH Foundation Trust

Appendix 6: Consent forms and PILs for the longitudinal clinical study described in Chapter II (Treatment group)

University College London Hospitals 
NHS Foundation Trust

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Identification Number for this study:Version 2 (08/10/2013)

ASSENT FORM
(Patient - Functional brace group)

Title of project: How do your teeth make you feel?
(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Professor Susan Cunningham, Professor Nigel Hunt, Ms Huda Abutayyem and Ms Aviva Petrie.

Please initial box

1. I have read and understood the information sheet (Version 2 dated 08-10-13) given to me for this study and I have asked all the questions I want to.

☐

2. I have had enough time to decide if I want to take part in the study.

☐


3. I know that it is up to me if I want to take part in this study and I can stop at any time if I want to.

☐

4. I agree to take part in the above study.

☐

Continued on next page/



University
College
Hospital

National Hospital
for Neurology and
Neurosurgery

Eastman
Dental
Hospital

Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine

The Eastman Dental Hospital

256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064

Contact e-mail: s.cunningham@ucl.ac.uk

Identification Number for this study:

Version 2 (08/10/2013)

ASSENT FORM

(Patient - Functional brace group)

Title of project: How do your teeth make you feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Professor Susan Cunningham, Professor Nigel Hunt, Ms Huda Abutayyem and Ms Aviva Petrie.

Name of participant

Date

Signature

Name of Person taking consent
(If different from researcher)

Date

Signature

Researcher (to be contacted
if there are any problems)

Date

Signature

Comments or concerns during the study

If you have any questions, comments, or concerns you may discuss these with a member of the research team. If you want to talk to someone who is not involved in the research, you may speak to any of the dentists in the Orthodontic Department.

uclh

University
College
Hospital

National Hospital
for Neurology and
Neurosurgery

Eastman
Dental
Hospital

Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

Version 2 (08-10-13)

CONSENT FORM

(Parent - Functional brace group)

Title of project: How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Professor Susan Cunningham, Professor Nigel Hunt, Ms Huda Abutayyem, and Ms Aviva Petrie

Please initial box

1. I confirm that I, and my child, have read and understood the information sheet (Version 2 dated 08-10-13) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I, and my child, have had sufficient time to consider whether or not to be included in the study. ☐
3. I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐
4. I understand that sections of my child's medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my child taking part in this research. I give permission for these individuals to have access to these records. ☐
5. I agree to my child taking part in the above study. ☐

Continued on next page/

uclh

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College
Hospital

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for Neurology and
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Eastman
Dental
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Royal National
Throat, Nose
and Ear Hospital

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WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

Version 2 (08/10/2013)

CONSENT FORM
(Parent - Functional brace group)

Title of project: How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt, Ms Huda Abutayyem, Ms Aviva Petrie.

Name of parent

Date

Signature

Name of Person taking consent
(If different from researcher)

Date

Signature

Researcher (to be contacted
if there are any problems)

Date

Signature

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient and parent to the best of my ability and in a way in which I believe s/he can understand.

Signed Date

Name (PRINT)

Comments or concerns during the study

If you or your child have any questions, comments, or concerns you may discuss these with a member of the research team. If you wish to talk to someone independent and who is not involved in the research, you may speak to any of the clinicians in the orthodontic department. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write to or get in touch with the Complaints Manager, UCL hospitals.

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Patient Information Leaflet

How do your teeth make you feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Invitation

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for taking the time to read this leaflet.

What is the purpose of the study?

We are interested in finding out how you feel about your teeth and how the look of your teeth makes you feel in a whole range of situations - for example, when you are at school, with your friends, doing other everyday activities etc. We are also trying to find out whether treatment with a removable "functional brace" makes you feel better in these situations. This research is being undertaken as part of an educational programme (a Ph.D degree in Orthodontics).

Why have I been invited?

You have been invited to join our study because you have a certain type of bite where the top teeth are further forward than the lower teeth and you have been offered treatment with a type of removable brace called a "functional brace" to correct your bite/teeth.

Do I have to take part?

No. It is up to you to decide. You do not have to take part in the study if you choose not to. If you do decide to do the study we will ask you and your parent/guardian to sign a consent form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without given a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

You will be asked to fill out a questionnaire twice: before the beginning of treatment (probably at your next visit) and at the end of the functional brace treatment (after about 9 to 12 months). The questionnaire will ask about your teeth and how you feel in certain situations, such as at school and when you are out with your friends. This should only take 15-20 minutes. There are no right or wrong answers; we are just interested in how you feel. You will not be asked to do anything else.

What will I have to do?

All you will be expected to do is to complete a questionnaire twice during your treatment as explained in the previous section.

What are the possible disadvantages or risks of taking part?

There are no risks expected. None of your answers will affect your treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for you individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Information regarding this is available if required.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the research will remain private. The information held about you will include the results of the questionnaires and also your age and gender (male or female). This information will be coded in such a way that you cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if I don't want to carry on with the study?

If you do not want to carry on with the study, you just need to let us know. This will not affect your brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish it. You will not be identifiable in any way.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayem or any of the other Orthodontists involved in your treatment.

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
Tel: 020 3456 1064
s.cunningham@ucl.ac.uk

Thank you for taking the time to read this leaflet

Parent Information Leaflet

How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Invitation

We would like to invite your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for taking the time to read this leaflet.

What is the purpose of the study?

We are interested in finding out how your child feels about their teeth and how the look of their teeth makes them feel in a whole range of situations - for example, when they are at school, with their friends, doing other everyday activities etc. We are also trying to find out whether treatment with a removable "functional brace" makes them feel better in these situations. This research is being undertaken as part of an educational programme (a Ph.D degree in Orthodontics).

Why has my child been invited?

Your child has been invited to participate because they have a certain type of bite where the top teeth are further forward than the lower teeth and they have been offered treatment with a removable brace called a "functional brace" to correct their bite/teeth.

Does my child have to take part?

No. It is up to you and your child to decide. They do not have to take part in the study if they or you choose not to. If your child decides to take part we will ask you and them to sign a consent form. If either of you change your mind, you are free to withdraw at any time, without giving a reason. The standard of care your child receives will not be affected in any way even if they decide not to take part.

What will happen to my child if they take part?

Your child will fill in a questionnaire twice: before the beginning of treatment and at the end of the functional brace treatment (in about 9 to 12 months time). The questionnaire will ask about their teeth and how they feel in certain situations. This should take no more than 15-20 minutes. There are no right or wrong answers; we just want to know their opinions. They will not be asked to do anything else.

What will they have to do?

All your child will be expected to do is to complete a questionnaire twice during your treatment as explained in the section above.

What are the possible disadvantages or risks of taking part?

There are no risks anticipated. None of the answers will affect your child's treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for your child individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given towards the end of this document.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. All information that is collected about them during the course of the research will remain private. The information held about them will include the results of the questionnaires and also their age and gender (male or female). This information will be coded in such a way that they cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if my child does not want to carry on with the study?

If your child does not want to carry on with the study, you just need to let us know. This will not affect their brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish. All information will be coded and your child will not be identifiable in any way.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayem or any of the other Orthodontists involved in your treatment.

Comments or concerns during the study

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0203-456-1064). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (<http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx>). Details can be obtained from any dentist working in the Orthodontic Department.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against UCLH Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
s.cunningham@ucl.ac.uk
Tel: 020 3456 1064

Thank you for taking the time to read this leaflet

Appendix 7: Consent forms and PILs for the longitudinal clinical study described in Chapter III (Control group)

University College London Hospitals 

NHS Foundation Trust

The Eastman Dental Hospital

256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Identification Number for this study:

Version 2 (08/10/2013)

ASSENT FORM

(Patient - Control group)

Title of project: How do your teeth make you feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Professor Susan Cunningham, Professor Nigel Hunt, Ms Huda Abutayem and Ms Aviva Petrie.

Please initial box

1. I have read and understood the information sheet (Version 2 dated 08-10-13) given to me for this study and I have asked all of the questions I want to.
2. I have had enough time to decide if I want to take part in this study.
3. I know that it is my decision as to whether I take part in this study and I understand that I can stop at any time if I wish to.
4. I agree to take part in the above study.

☐☐☐☐

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Contact e-mail: s.cunningham@ucl.ac.uk

Identification Number for this study:

Version 2 (08/10/2013)

ASSENT FORM
(Patient - Control group)

Title of project: How do your teeth make you feel?
(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Professor Susan Cunningham, Professor Nigel Hunt, Ms Huda Abutayyem and Ms Aviva Petrie.

Name of participant Date Signature

Name of Person taking consent
(If different from researcher) Date Signature

Researcher (to be contacted
if there are any problems) Date Signature

Comments or concerns during the study

If you have any questions, comments, or concerns you may discuss these with a member of the research team. If you want to talk to someone who is not involved in the research, you may speak to any of the dentists in the Orthodontic Department.

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256 Gray's Inn Road

London

WC1X 8LD

Direct line: 020 3456 1064

Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

Version 2 (08/10/2013)

CONSENT FORM

(Parent - Control group)

Title of project: How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt, Ms Huda Abutayyem, Ms Aviva Petrie

Please initial box

1. I confirm that I, and my child, have read and understood the information sheet (Version 2 dated 08-10-13) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I, and my child, have had sufficient time to consider whether or not to be included in the study. ☐
3. I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐
4. I understand that sections of any of my child's medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my child taking part in this research. I give permission for these individuals to have access to these records. ☐
5. I agree to my child taking part in the above study. ☐

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Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

Version 2 (08/10/2013)

CONSENT FORM

(Parent - Control group)

Title of project: How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt, Ms Huda Abutayyem, Ms Aviva Petrie.

_____	_____	_____
Name of parent	Date	Signature
_____	_____	_____
Name of Person taking consent (If different from researcher)	Date	Signature
_____	_____	_____
Researcher (to be contacted if there are any problems)	Date	Signature

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient and parent to the best of my ability and in a way in which I believe s/he can understand.

Signed Date

Name (PRINT)

Comments or concerns during the study

If you or your child have any questions, comments, or concerns you may discuss these with a member of the research team. If you wish to talk to someone independent and who is not involved in the research, you may speak to any of the clinicians in the orthodontic department. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write to or get in touch with the Complaints Manager, UCL hospitals.

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Patient Information Leaflet

How do your teeth make you feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Invitation

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for taking the time to read this leaflet.

What is the purpose of the study?

We are interested in finding out how people feel about their teeth and how the look of their teeth makes them feel in a whole range of situations - for example, at school, with friends, doing other everyday activities etc. We also want to know if treatment with a brace makes people feel better in these situations. To do this research, we need to compare a group of patients who have already started brace treatment with a group who have not yet got braces (this group is sometimes called a "control group"). We can then compare the results for the two groups. This research is being undertaken as part of an educational programme (a Ph.D degree in Orthodontics).

Why have I been invited?

You have been invited to take part because you are being seen at the hospital about your teeth but you have not started any brace treatment yet.

Do I have to take part?

No. It is up to you to decide. You do not have to take part in the study if you choose not to. If you do decide to do the study we will ask you and your parent/guardian to sign a consent form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without given a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

You will fill out a questionnaire twice: now and then when you are seen again in our department for a routine review appointment (probably in about 6 to 12 months). The questionnaire will ask about your teeth and how you feel in certain situations, such as at school and when you are out with your friends. This should take no more than 15-20 minutes. There are no right or wrong answers; we are just interested in how you feel.

What will I have to do?

All you will be expected to do is to complete a questionnaire twice as explained in the section above. You will not be asked to do anything else.

What are the possible disadvantages or risks of taking part?

There are no risks expected. None of your answers will affect your treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for you individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Information regarding this is available if required.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the research will remain private. The information held about you will include the results of the questionnaires and also your age and gender (male or female). This information will be coded in such a way that you cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if I don't want to carry on with the study?

If you do not want to carry on with the study, you just need to let us know. This will not affect your brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish it. You will not be identifiable in any way.

Will my taking part in the study remain confidential?

Yes. All information that is collected about you during the study will remain private. The information held about you will include the results of the questionnaires and also your age and gender (male or female). This information will be coded in such a way that you cannot be identified in any way.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayyem or any of the other Orthodontists involved in your treatment.

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
s.cunningham@ucl.ac.uk and Tel: 020 3456 1064

Thank you for taking the time to read this leaflet

Parent Information Leaflet

How your child's teeth make them feel?

(A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents)

Invitation

We would like to invite your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for reading this leaflet.

What is the purpose of the study?

We are interested in finding out how people feel about their teeth and how the look of their teeth makes them feel in a whole range of situations - for example, at school, with friends, doing other everyday activities etc. We also want to know if treatment with a brace makes people feel better in these situations. To do this study, we need to compare a group of patients who have already started brace treatment with a group who have not yet got braces (this group is sometimes called a "control group"). We can then compare the results for the two groups. This research is being undertaken as part of an educational programme (a Ph.D degree in Orthodontics).

Why has my child been invited?

Your child has been invited to take part because they are being seen at the hospital about their teeth but has not started any brace treatment yet.

Do they have to take part?

No. It is up to you and your child to decide. They do not have to take part in the study if they or you choose not to. If your child decides to take part we will ask you and them to sign a consent form. If either of you change your mind, you are free to withdraw at any time, without giving a reason. The standard of care your child receives will not be affected in any way even if they decide not to take part.

What will happen to my child if they take part?

Your child will fill in a questionnaire twice: now and then when they are seen again in our department for a routine review appointment (probably in about 6 to 12 months). The questionnaire will ask about their teeth and how they feel in certain situations. This should take no more than 15-20 minutes. There are no right or wrong answers; we just want to know their opinions. They will not be asked to do anything else.

What will my child have to do?

All your child will be expected to do is to complete a questionnaire twice as explained in the section above.

What are the possible disadvantages or risks of taking part?

There are no risks expected. None of their answers will affect their treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for your child individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given towards the end of this document.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. All information that is collected about them during the course of the research will remain private. The information held about them will include the results of the questionnaires and also their age and gender (male or female). This information will be coded in such a way that they cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if my child does not want to carry on with the study?

If your child does not want to carry on with the study, you just need to let us know. This will not affect their brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish it. You will not be identifiable in any way.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayyem or any of the other Orthodontists involved in your treatment.

Comments or concerns during the study

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0203-456-1064). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (<http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx>). Details can be obtained from any dentist working in the Orthodontic Department.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against UCLH Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
s.cunningham@ucl.ac.uk and Tel: 020 3456 1064

Thank you for taking the time to read this leaflet

Appendix 8: Letter to go out with appointments to aid control group recruitment

University College London Hospitals

NHS Foundation Trust

The Eastman Dental Hospital

256 Gray's Inn Road

London

WC1X 8LD

Direct line: 020 3456 1064

Contact e-mail: s.cunningham@ucl.ac.uk

Publication date: 01-10-13
Date last reviewed: 01-10-13
Version: 1

Patient Information Leaflet

How do your teeth make you feel?

You and your child are about to attend an appointment in the Orthodontic Department at the Eastman Dental Hospital. In many hospitals in the UK, research is an important part of day to day work and the Eastman Dental Hospital is a world leading research centre.

One of the studies we are doing at the moment in the Orthodontic Department is trying to find out how children and adolescents (10-14 year olds) feel about their teeth and how the look of their teeth makes them feel in a whole range of social situations - for example, when they are at school, with friends, doing other everyday activities etc. We are also trying to find out whether treatment with braces makes patients feel better in these situations. This research is being undertaken as part of an educational programme (a PhD degree in Orthodontics).

If your child fits the criteria to be included in this study, one of the researchers will speak to you both and invite your child to join the study. You will be given plenty of information regarding what is involved.

You do not have to take part in the study if you choose not to and it will not affect treatment in any way if you choose not to be involved. If you do decide to do the study we will ask you both to sign a consent form and then your child will be asked to fill out a questionnaire twice: in the near future and then again in about 9 months' time.

There are no risks expected and none of your answers given will affect treatment in any way. We cannot promise the study will help your child but the information we get from this study will help improve the treatment of people who have problems with their teeth/bite.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the research will remain private.

Many thanks for reading this letter and we look forward to seeing you when you attend for your appointment.

Contact details for the research team:

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem

Department of Orthodontics, Eastman Dental Hospital and Institute

256 Gray's Inn Road, London, WC1X 8LD Tel: 020 3456 1064 s.cunningham@ucl.ac.uk

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Appendix 9: Ethical approval for the qualitative study (Chapter IV)



NRES Committee London - Chelsea

Research Ethics Committee (REC) Bristol Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1380

24 December 2014

Professor Susan Cunningham
Professor/Hon Consultant in Orthodontics
Department of Orthodontics
UCL Eastman Dental Institute
256 Grays Inn Road
London
WC1X 8LD

Dear Professor Cunningham

Study title:	A qualitative study to investigate the effects of malocclusion
REC reference:	13/LO/1256
Amendment number:	Substantial Amendment 2
Amendment date:	22 October 2014
IRAS project ID:	128743

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee approved the following changes:

1. Inclusion of patient interviews to investigate the social impacts of having dental problems.
2. Changes to inclusion criteria:
 - a. Inclusion of 12-16 year old children instead of 10-14 year old children.
 - b. Inclusion of children with other types of dental bite in order to consider whether there are any differences.
3. Participant Information Sheets and Protocol have been updated.
4. Inclusion of a Topic Guide for the Interviews.

5. Change in study title to reflect interviews are involved in the study: "A qualitative study to investigate the effects of malocclusion".

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Interview schedules or topic guides for participants [Interview Topic Guide]	1	22 October 2014
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 2	22 October 2014
Participant consent form [Parent (Tracked Copy)]	1	22 October 2014
Participant consent form [Patient Assent Form (Tracked Copy)]	1	22 October 2014
Participant information sheet (PIS) [Patient (Tracked Copy)]	1	22 October 2014
Participant information sheet (PIS) [Parent (Tracked Copy)]	1	23 October 2014
Research protocol or project proposal [(Tracked Copy)]	4	22 October 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/LO/1256:	Please quote this number on all correspondence
-------------	--

Yours sincerely

pp Ms Stephanie Ellis
Chair

E-mail: nrescommittee.london-chelsea@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Miss Tabitha Kavoï, RandD@uclh.nhs.uk*

NRES Committee London - Chelsea

Attendance at Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Stephanie Ellis (Chair)	Lay Member	Yes	
Dr Elliot Shinebourne	Consultant Paediatric Cardiologist	Yes	
Mrs Paula Rogers	Cardiology Research Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Gemma Oakes	REC Manager

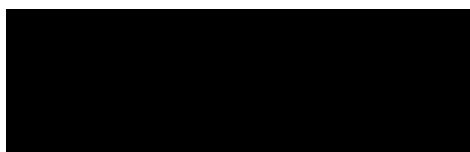
Appendix 10: Certificates for attendance on the Qualitative courses at NatCen

NatCen LEARNING
Social Research that works for society

Certificate of attendance

Depth interviewing skills
25th & 26th June 2013

This is to certify that
Huda Abutayyem
Attended this two day training course



Director: NatCen Learning

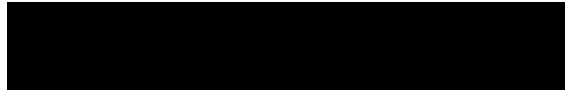
The course provided theoretical and practical training in the range of different skills and techniques required to conduct in-depth interviews to a high standard. The sessions covered included: listening and questioning skills; the use of probes to elicit depth; design and use of topic guides; and effective management of the in-depth interview process.

The course was delivered by experienced practitioners from
NatCen's Research Department, on behalf of NatCen Learning at
NatCen Social Research

Certificate of attendance

The analysis of qualitative data
12th & 13th June 2013

This is to certify that
Huda ABUTAYYEM
Attended this two day training course



Director: NatCen Learning

The course provided intensive training in qualitative data analysis (QDA) using both taught and practical sessions. The sessions covered: the nature of the analytical task in qualitative research, the range of approaches to data management, the tools available for QDA, and interpretative techniques for the generation of high quality, robust research findings.

The course was delivered by experienced practitioners from the Research Department at the NatCen Social Research on behalf of NatCen Learning

Appendix 11: Topic guide for the qualitative study (Chapter IV)

TOPIC GUIDE Version 1 (22-10-14)

University College London Hospitals 
NHS Foundation Trust

eastman DENTAL
INSTITUTE

Topic Guide

Impacts of malocclusion in adolescent patients

Objectives

- To determine the effects as a result of having a malocclusion
- To gather information as a result of their experience as having malocclusion
- To understand the needs of the treatment

Introduction

- Confidentiality

Introduction

(Aim: to explain the purpose of the research, introduce researcher)

Thank interviewee for taking part in the research

Introduce self

Explain purpose of the research

If at any point, they would like to take a break, just to say

Reassure: confidentiality - nothing you say will be linked to your name, recoding.

Explain importance of interviewee saying what they think, there are no right or wrong answers, all opinions valid and helpful

Check interviewee is comfortable with interview format. Any questions?

General introduction to make the patient feel at ease e.g. ask name, age, interests, family

Impact of malocclusion (Aim: To explore the impacts)
Discuss aspects of the subject's teeth they like or dislike: e.g. shape, colour, size, position, crooked, straight, bite (how do you think braces might improve this?)
Discuss why they would like to have orthodontic treatment? Use previous comments re concerns about the teeth and start to discuss potential impacts
Commence sensitive exploration regarding home, school, social networks and whether their malocclusion has ever affected these interactions
Exploration of situations which they may have found difficult; any activities they may avoid because of concerns regarding their teeth (particularly social situations)
Possible prompts if needed (but avoid leading questions): <ul style="list-style-type: none"> • Relationships with other people? Friends/Family/Other contacts? Any effects? • Effects when meeting new people/friends? • Effects at school and at any social clubs/activities they participate in? • Avoidance of having photos taken? Feelings re photos on social media sites (de-tagging, removing)? • Other situations where there has been an impact? • Other effects e.g. bullying/name calling?

Summary (Aim: to round up the interview and close)
Is there anything else that you'd like to discuss?
Any questions?

Thank the patient and close

Appendix 12: Consent forms and PILs for the qualitative study (Chapter IV)



University College London Hospitals



NHS Foundation Trust

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064

Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

ASSENT FORM

How do your teeth make you feel?
(A qualitative study to investigate the effects of malocclusion)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem

Please initial box

1. I have read and understood the information sheet (Version 1 dated 23-10-14) for the above study and have had the opportunity to ask questions. ☐
2. I have had enough time to decide if I want to take part in the study. ☐
3. I know that it is my decision as to whether I take part in this study and I understand I can stop at any time if I wish to ☐
4. I know that some parts of my medical notes and data collected during the study may be looked at by individuals from University College London, from regulatory authorities or from the NHS Trust, where it is relevant to this research. I give permission for these individuals to have access to my records. ☐
5. I agree that my interview can be tape recorded
This recording will then be destroyed but some quotes from the recordings may be used in publications – these will never include your name. ☐
6. I agree to take part in the above study ☐

uclh

Part 2 Qualitative study: Assent form Version 1 (22-10-14) (Student Study)

University
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National Hospital
for Neurology and
Neurosurgery

Eastman
Dental
Hospital

Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine

Page 1 of 2



University College London Hospitals



NHS Foundation Trust

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Patient Identification Number for this study:

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

ASSENT FORM

How do your teeth make you feel?
(A qualitative study to investigate the effects of malocclusion)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem

Name of patient

Date

Signature

Name of Person taking consent
(If different from researcher)

Date

Signature

Researcher

Date

Signature

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient and parent to the best of my ability and in a way in which I believe s/he can understand.

Signed Date

Name (PRINT)

Comments or concerns during the study

If you or your child have any questions, comments, or concerns you may discuss these with a member of the research team. If you wish to talk to someone independent and who is not involved in the research, you may speak to any of the clinicians in the orthodontic department. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write to or get in touch with the Complaints Manager, UCLH or with the Patient Advice and Liaison Service at UCLH (Tel No: 020 3447 3042). Please quote the UCLH project number at the top this consent form.



Part 2 Qualitative study: Assent form Version 1 (22-10-14) (Student Study)

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University
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National Hospital
for Neurology and
Neurosurgery

Eastman
Dental
Hospital

Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine



University College London Hospitals **NHS**
NHS Foundation Trust

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

CONSENT FORM

How do your child's teeth make them feel?
(A qualitative study to investigate the effects of malocclusion)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem

Please initial box

1. I confirm that I, and my child, have read and understood the information sheets (Version 1 dated 23-10-14) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I, and my child, have had sufficient time to consider whether or not to be included in the study ☐
3. I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐
4. I understand that sections of any of my child's medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my child taking part in this research. I give permission for these individuals to have access to these records. ☐
5. I agree that the interview can be tape recorded.
This recording will then be destroyed but some quotes from the recordings may be used in publications – these will never include your child's name. ☐
6. I agree to my child taking part in the above study ☐

uclh

Part 2 Qualitative study: Consent form Version 1 (22-10-14) (Student Study)

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Hospital for
Integrated Medicine



University College London Hospitals



NHS Foundation Trust

The Eastman Dental Hospital
256 Gray's Inn Road
London
WC1X 8LD

Direct line: 020 3456 1064
Contact e-mail: s.cunningham@ucl.ac.uk

Patient Identification Number for this study:

CONSENT FORM

How do your child's teeth make them feel?
(A qualitative study to investigate the effects of malocclusion)

Name of researchers: Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem

_____ Name of Parent	_____ Date	_____ Signature
_____ Name of Person taking consent (If different from researcher)	_____ Date	_____ Signature
_____ Researcher	_____ Date	_____ Signature

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient and parent to the best of my ability and in a way in which I believe s/he can understand.

Signed Date

Name (PRINT)

Comments or concerns during the study

If you or your child have any questions, comments, or concerns you may discuss these with a member of the research team. If you wish to talk to someone independent and who is not involved in the research, you may speak to any of the clinicians in the orthodontic department. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write to or get in touch with the Complaints Manager, UCLH or with the Patient Advice and Liaison Service at UCLH (Tel No: 020 3447 3042). Please quote the UCLH project number at the top of this consent form.



Part 2 Qualitative study: Consent form Version 1 (22-10-14) (Student Study)

Page 2 of 2

University
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Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine

Patient Information Leaflet

How do your child's teeth make them feel?
(A qualitative study to investigate the effects of malocclusion)

Invitation

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for taking the time to read this leaflet.

What is the purpose of the study?

We are interested in finding out how you feels about their teeth and how the look of their teeth makes them feel in a whole range of situations - for example, when you are at school, with your friends, doing other everyday activities etc. This research is being undertaken as part of an educational programme (a PhD degree in Orthodontics).

Why have I been invited?

You have been invited to join our study because you have been offered treatment to correct your bite/teeth.

Do I have to take part?

No. It is up to you to decide. You do not have to take part in the study if you choose not to. If you do decide to do the study we will ask you and your parent/guardian to sign a consent form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without given a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

Ms Abutayyem or Professor Cunningham will have a discussion with you about your teeth and how you feel in certain situations, such as at school and when you are out with your friends. This should take between 15-20 minutes depending on how much you wish to say. The discussion will be audio recorded and then typed up and anonymised. The recording will be deleted after that. There are no right or wrong answers; we are just interested in how you feel. You will not be asked to do anything else.

What will I have to do?

All you will be expected to do is to have one short discussion during your treatment as explained in the previous section.

What are the possible disadvantages or risks of taking part?

There are no risks expected. We are not expecting any of your answers to affect your treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for you individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

Will my taking part in the study be kept confidential?



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College
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Neurosurgery

Eastman
Dental
Hospital

Royal National
Throat, Nose
and Ear Hospital

Heart
Hospital

Royal London
Hospital for
Integrated Medicine

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the research will remain private. The information held about you will include the analysis of the interviews and also your age and gender (male or female). This information will be coded in such a way that you cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if I don't want to carry on with the study?

If you do not want to carry on with the study, you just need to let us know. This will not affect your brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish it. You will not be identifiable in any way.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London-Chelsea Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayyem or any of the other Orthodontists involved in your treatment.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service (<http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/Pages/AboutNHSComplaints.aspx>) or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of University College London or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Susan Cunningham who is the Chief Investigator for the research and is based at UCL Eastman Dental Institute. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayyem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
Tel: 020 3456 1064
s.cunningham@ucl.ac.uk

Thank you for taking the time to read this leaflet

Parent Information Leaflet

How do your child's teeth make them feel?
(A qualitative study to investigate the effects of malocclusion)

Invitation

We would like to invite your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for your child. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us about anything which is not clear. Thank you for taking the time to read this leaflet.

What is the purpose of the study?

We are interested in finding out how your child feels about their teeth and how the look of their teeth makes them feel in a whole range of situations - for example, when you are at school, with your friends, doing other everyday activities etc. This research is being undertaken as part of an educational programme (a PhD degree in Orthodontics).

Why have I been invited?

Your child has been invited to join our study because they have been offered treatment to correct your bite/teeth.

Do I have to take part?

No. It is up to you to decide. You do not have to take part in the study if you choose not to. If you do decide to do the study we will ask you and your parent/guardian to sign a consent form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without given a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

Ms Abutayem or Professor Cunningham will have a discussion with your child about their teeth and how they feel in certain situations, such as at school and when you are out with your friends. This should take between 15-20 minutes depending on how much you wish to say. The discussion will be audio recorded and then typed up and anonymised. The recording will be deleted after that. There are no right or wrong answers; we are just interested in how you feel. They will not be asked to do anything else.

What will I have to do?

All you will be expected to do is to have one short discussion during your treatment as explained in the previous section.

What are the possible disadvantages or risks of taking part?

There are no risks expected. We are not expecting any of your answers to affect your treatment in any way.

What are the benefits of taking part?

Although there may not be any direct benefit for your child individually, we hope that in the future the findings from this study will help people who have problems with their teeth/bite and who want to have brace treatment.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the research will remain private. The information held about your child will include the analysis of the interviews and also their age and gender (male or female). This information will be coded in such a way that they cannot be identified in any way. The data will be stored until we are certain we do not need to look at it again for any reason – when we are certain this is the case, we will destroy it safely.

What will happen if I don't want to carry on with the study?

If your child does not want to carry on with the study, you just need to let us know. This will not affect their brace treatment in any way. We will however use the information up to the point where you tell us.

What will happen with the results of the study?

We hope to publish the results of this study when we finish it. You will not be identifiable in any way.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London-Chelsea Research Ethics Committee. If you would like to see a summary of the findings from the study when it is completed, please tell Mrs Abutayem or any of the other Orthodontists involved in your treatment.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service (<http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/Pages/AboutNHSComplaints.aspx>) or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of University College London or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Susan Cunningham who is the Chief Investigator for the research and is based at UCL Eastman Dental Institute. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Contact details

Prof Susan Cunningham, Prof Nigel Hunt and Mrs Huda Abutayem
Department of Orthodontics, Eastman Dental Hospital and Institute
256 Gray's Inn Road, London, WC1X 8LD
Tel: 020 3456 1064
s.cunningham@ucl.ac.uk

Thank you for taking the time to read this leaflet

Appendix 13: The written agreement between the transcription company and UCLH R & D

AGREEMENT FOR THE PROVISION OF SERVICES

This Agreement shall commence or be deemed to have commenced on the *date of last signature*.

BETWEEN (1) **UCL Hospitals NHS Foundation Trust ("UCLH")**, hereby represented by the Joint Research Office ("JRO"), of Gower Street, London, WC1E 6BT (together "the Sponsor")

AND (2) **The Typing Works** (7 Ingle Close, Pinner, Middx HA5 3BJ) ("the Company")

WHEREAS

(A) The Sponsor has identified a need for audio recorded interviews to be transcribed (as further described in Schedule 1 attached hereto) (the Services") in the study entitled "**A prospective controlled questionnaire study to investigate the social effects of malocclusion and orthodontic treatment in a cohort of Class II division 1 adolescents**" ("the Trial").

(B) The Company has the required level of expertise and has agreed to provide the Services to the Sponsor for the Trial under the terms of this Agreement.

IT IS HEREBY AGREED THAT

1. Definitions

The following words and phrases in this Agreement have the meanings set out here:

"**Framework**" means the 'Research Governance Framework for Health and Social Care' issued by the UK Department of Health (Second Edition 2005) or the 'Scottish Health Department Research Governance Framework for Health and Community Care' (Second Edition 2006), (Scottish Sites Only) or the 'Research Governance Framework for Health and Social Care in Wales' (second edition 2009), (Welsh Sites only), as may be amended from time to time;

"**GCP**" refers to the principles of ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as set out in Schedule 1 (Conditions and Principles of Good Clinical Practice and for the Protection of Clinical Trial Subjects) of the Medicines for Human Use (Clinical Trials) Regulations 2004 and the GCP Directive 2005/28/EC, as set out in SI 2006/1928, and any amendments thereto;

"**Intellectual Property**" means all patents, trademarks, copyrights, database rights, design rights and all rights (whether registered or unregistered) or forms of protection of a similar nature or having equivalent or similar effect to any of them anywhere in the world, whether registered or not and including applications for registration of any of them;

"**Know How**" means all technical and other information which is not in the public domain, including information relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests, the results of experiments and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information whether or not contained in submissions to regulatory authorities;

"**Sponsor**" means the organisation that takes responsibility for the initiation, management and financing (or arranging the financing) of the Trial;

Page 1 of 7

Agreement for the provision of services for the study with the short title "How do your teeth make you feel?" adapted by FT on 04.06.2015

“Site” means the hospital or any premises in which the Trial will be conducted and which is approved by the applicable NHS Trust or Health Board.

2. Agreement

In consideration of the payment of the agreed fees and charges as set out in clause 2 hereof, the Company shall perform the Services for the duration of the Trial, unless this Agreement is terminated in early in accordance with clause 9. The Company shall perform the Services in accordance with:

- (a) All applicable laws and regulations, where applicable, including but not limited to the Human Rights Act 1998, the Data Protection Act 1998, The Freedom of Information Act 2000, The Human Tissue Act 2004, the Medicines Act 1968 and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, GCP, the World Medical Association Declaration of Helsinki entitled *'Ethical Principles for Medical Research Involving Human Subjects'* (1996 version), the Framework and any amendments to any of the foregoing.

3. Fees & Charges

3.1 The Sponsor/Sponsor's designee shall pay to the Company the sum of £8.00 per thousand words (excl. VAT) for the provision of the Services, upon receipt of an invoice from the Company, which shall be sent bi-monthly in arrears.

3.2 All amounts provided to the Company under this Agreement shall be made payable by bank transfer to the following account of Company within thirty (30) days from receipt by the Sponsor's designee of an itemized invoice:

Invoices to be sent to:

Name: Susan Cunningham
Title: Professor

Email: s.cunningham@ucl.ac.uk
Telephone: 0203 456 1064
Reference: Abu Tayyem PhD Research

Post Address: Eastman Dental Hospital, Dept of Orthodontics, 256 Grays Inn Road, London, WC1X 8LD
Courier Address: As above

Payments to be made to :

Account name: The Typing Works Limited
Account address: Customer Service Centre, Bootle, Merseyside L30 4GB UK
Account number: 37250344
Sort code: 09-01-27
Finance Department details:
Tel: 0208 868 0385

Payment reference number (must be quoted when making payments) : (I.e. Individual account number on invoice)

4. The Company's Obligations

Page 2 of 7

Agreement for the provision of services for the study with the short title “How do your teeth make you feel?” adapted by FT on 04.06.2015

3.1 The Company shall provide the Services as required and ensure the performance and observance by its employees of its obligations under this Agreement to:

- (b) unless prevented by ill health or accident, efficiently and diligently perform the Services as may from time to time be reasonably and lawfully assigned by the Sponsor;
- (c) co-operate with the Sponsor's staff and accept the direct supervision and proper instruction of superiors in the Sponsor's organisation;
- (d) observe any applicable and lawful rules, regulations, policies or procedures of the Sponsor's establishment;
- (e) under no circumstances to allow any data belonging to the Sponsor to be copied or stored on a laptop or portable storage device that will leave the Sponsor's premises, unless the laptop or portable device is fully encrypted to the Sponsor's approved standards;
- (f) not engage in any conduct detrimental to the interests of the Sponsor;
- (g) not at any time divulge to any person, nor use for its own or any person's benefit, any confidential information in relation to the Sponsor's employees, business affairs, transactions or finances;
- (h) be familiar with and comply with the relevant terms of this Agreement.

3.2 The Company warrants that it has appropriate insurance coverage to cover its performance of the Services hereunder.

5. The Sponsor's Obligations

The Sponsor shall, at its own expense:

5.1 Provide the Company with all documents or other materials and data or other information necessary for the provision of the Services, in sufficient time to enable the provision of Services in accordance with any timetable or other target for progress or completion as agreed between the parties.

5.3 Procure that the Company are accorded appropriate access to the Sponsor's or Sites' premises and/or materials that is reasonably necessary for the provision of the Services.

6. Liability

The Company shall be liable for and indemnify the Sponsor against all demands, claims, losses or costs arising due to its wilful misconduct and/or negligent acts and/or omissions in the course of or in connection with this Agreement.

7. Data and Intellectual Property

Any Know-How related to the Trial shall belong to the Sponsor. Any arising Intellectual Property under this Agreement shall be disclosed to the Sponsor shall belong to and be the absolute property of the Sponsor. The Company will assign to the Sponsor, as appropriate, any rights they may have to Know-How/Intellectual Property arising from the Services carried out under this Agreement.

8. Confidentiality and Data Protection

- 8.1 The Company will act in accordance with all Company policies and all applicable laws, principles, and guidance regarding confidentiality and data protection; keep confidential any information acquired during the period of this agreement concerning the Sponsor's research, development, commercial plans and activities; and agree not to disclose such information to any third party at any time hereinafter without prior written consent of the Sponsor, save where such information is already in the public domain through no fault of the parties, and where the parties are required by law to make a disclosure, provided that prior to such disclosure, the Company shall notify the Sponsor of its obligation to disclose the Sponsor's confidential information and the Sponsor shall be permitted to advise the Company of the proposed form of disclosure.
- 8.2 Both parties shall take all reasonable steps to ensure that any documents or other materials and data or other information which are supplied in the provision of the services and are clearly marked as confidential, remain confidential to the parties. The parties will only make such information available to those personnel who have a reasonable need to know of it and the documents or other materials and data or other information or copies thereof will not be made available to any third parties.
- 8.3 Both parties undertake that any information which is received from the other party in the provision of services will only be used for the purposes of this Agreement.
- 8.4 The Company may not use the name of the Sponsor in any advertising or promotional material for its products or services without the written consent of the Sponsor, not to be unreasonably withheld.
- 8.5 This clause 8 will remain in force beyond the cessation or other termination of this Agreement for five (5) years thereafter.

9. Early Termination

- 9.1 Either party may terminate this Agreement immediately by written notice to the other party in the event that:
- (a) either party is in material breach of this Agreement and fails to remedy such breach (if capable of remedy) within five working days after being required in writing to do so
 - (b) the other party goes into liquidation or becomes bankrupt, makes a voluntary arrangement with its creditors or has a receiver or administrator appointed.
- 9.2 The Sponsor may terminate this Agreement without cause upon thirty (30) days' written notice.

10. General

- 10.1 If the performance by a party of its obligations under this Agreement is delayed by reasons beyond its reasonable control ("Force Majeure"), the affected party shall promptly notify the other party, specifying the details of the delay and how long it expects the delay to continue. In the event the Force Majeure lasts for more than four (4) weeks, the unaffected party shall be entitled to terminate this Agreement forthwith on written notice to the other party.
- 10.2 The parties to this Agreement are independent organisations and nothing in this Agreement or by virtue of performing it shall be taken as creating a relationship of agent to principal, employer to employee, partnership or joint venture between the Sponsor and the Company. Neither party shall be entitled to enter into agreements or other arrangements on behalf of the other.

- 10.3 The Company is responsible for any tax and national insurance liability whatsoever in respect of its employees and agrees to indemnify the Sponsor in full for any assessment of tax or national insurance made against the Sponsor by the Inland Revenue or Contributions Agency in respect of such employees.
- 10.4 The Company may not assign its rights under this Agreement, or any part of it, or subcontract the performance of any of its obligations, without the prior written consent of the Sponsor. If the Company does subcontract its obligations, it shall remain responsible for the acts and omissions of its sub-contractors as if they were its own employees.
- 10.5 The terms of this Agreement, including its Schedules, represent the entire agreement between the parties and supersede any previous representations or agreements whether recorded in writing or otherwise.
- 10.6 Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier or by recorded delivery post.

Notices to the Company shall be addressed to:

The Typing Works Ltd
7 Ingle Close
Pinner
Middx HA5 3BJ

Notices to the Sponsor shall be addressed to:

Research Contracts Manager
Joint Research Office
UCL
Gower Street
London WC1E 6BT

- 10.7 Both parties agree that the terms of this Agreement are fair and reasonable in all the circumstances.
- 10.8 It is agreed that this Agreement shall be governed and construed according to the laws of England and Wales and the parties submit to the non-exclusive jurisdiction of the English Courts.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their officers hereunto duly authorised.

Signed on behalf of the Sponsor by

 **JOE MWANZA**
HEAD OF
FINANCE

Date 26/6/15

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Agreement for the provision of services for the study with the short title "How do your teeth make you feel?" adapted by FT on 04.06.2015

Signed on behalf of the Company by

A black rectangular box redacting the signature of Adele Herson.

Date 22nd June 2015

Adele Herson
Managing Director
The Typing Works Ltd

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Agreement for the provision of services for the study with the short title "How do your teeth make you feel?" adapted by FT on 04.06.2015

Schedule 1: Services

The service required will be transcription of audio recordings of interviews undertaken as part of a qualitative research study.

This will include:

1. Receipt of the audio recordings in digital format (uploaded via the Hightail secure facility); these will be sent as and when the interviews are undertaken rather than sending as a batch of interviews. It is anticipated that between 10 and 20 transcripts will require transcription.
2. Transcription of audio recordings within 10 days of receipt
3. Encryption and return of the typed transcripts
4. All audio recordings and typed transcripts will be deleted following safe receipt by the researchers.

Appendix 14: Excerpt of Framework Analysis

chart 1: Interpersonal relations				
Order	Analytical format	1.1 interacting with people they already know	1.2 Meeting new people	1.3 effects
P1		<p>So you said that you not worried I think when you are meeting your classmates? (152) Not really with my friends, but a little bit more with my classmates (155). You're a little bit worried? (157) Yeah (159). Just in the school with friends that you are trying to avoid laughing? (233) Yeah, sometimes (235). So do you think that you are thinking about it all the time or just when you are laughing or something? (252) It's most of time, just sort of reminding myself to like close my mouth (255). It must be very difficult (257). It's just sort of aware (259). What about when you are with your family or with your family friends, neighbours, how you feel with them?(269) It's okay 'cos sort of I don't really mind what they think of me 'cos they're my family and they can't do anything except to be nice to me so yeah it's fine (272).</p>	<p>What about meeting new people? (175) It's not too bad when you're meeting new people because like you won't really comment like if you're just meeting someone, you're not going to comment on how they look so it's fine (177). So it's fine meeting new people, you have no problems? (180) Not really, no (182)</p>	
P2		<p>How does that make you feel or when you're worried about your teeth, every time or when you're at school, friends? (146) No, I actually don't worry, like my friends are nice so they don't really care about how your teeth look like or not (149)</p>	<p>So you're not worried with your friend, what about meeting new people?(152) I don't mind, no, I don't have any problems (154).</p>	<p>Does this colleague activities</p>

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